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Development and validation of an anaesthetic consent form

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg in partial fulfilment of the requirements for the degree of Master of Medicine in the branch of Anaesthesiology.

Johannesburg, 2021

Declaration

I, Karyll Mae San Pedro declare that this research report is my own unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



26 March 2021

Abstract

Background

Informed consent is an integral part of daily anaesthetic practice. It is an important clinical entity as well as a medico-legal obligation to inform patients of the risks of anaesthesia. The aim of this study was to develop and validate an anaesthetic consent form for surgery at the University of Witwatersrand affiliated hospitals

Methods and results

A prospective, exploratory and instrumental design was used for the study. Purposive sampling was used in Lynn's two-stage Model of determination and quantification of content validity. The first stage, the Development Stage, involved an extensive review of the literature, which was followed by a peer group discussion. Local experts debated each item until 100% consensus was reached. The revised anaesthetic consent form consisted of 95 items. The Judgement/Quantification Stage involved 10 national experts using a four-point Likert scale for rating and validation. Items that were rated 3 or 4 were considered content valid. This resulted in 65 of 95 items being considered content valid. The revised anaesthetic consent form received a content validity index (CVI) of 0.68. Lynn suggests that for an instrument to be considered content valid, a minimum CVI of 0.8 should be obtained.

Conclusion

The CVI of the final instrument did not meet content validity requirements. However, the principle of informed consent remains important in good anaesthesia practice as it is an ethical and legal requirement to obtain before any procedure. Further research is required to develop the optimal anaesthesia consent form.

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Table of contents

Declaration ii

Abstract iii

Acknowledgements iv

Abbreviations x

Statement xi

Section 1: Review of the literature 1

1.1 Introduction 1

1.2 History of informed consent 1

1.3 The concept of informed consent 3

1.4 Types of consent 8

1.5 Limitations on obtaining true informed consent 9

1.6 Need for a separate anaesthetic consent 9

1.7 Ethical and legal considerations of informed consent 10

1.8 Legislation and regulations regarding informed consent in South Africa 11

1.9 South African Society of Anaesthesiologists and informed consent 14

1.10 Development and validation of an anaesthetic consent form 16

1.11 Summary 17

1.12 References 18

Section 2: Author's guidelines 23

Section 3: Draft article 29

Section 4: Proposal 48

4.1 Introduction and problem statement 49
4.2 Aim and objectives 51
4.2.1 Aim 51
4.2.2 Objectives 51
4.3 Research assumptions 51
4.4 Ethical considerations 52
4.5 Research methodology 53
4.5.1 Research design 53
4.5.2 Study method 53
4.5.3 Study population 53
4.5.4 Study sample and sample method 53
4.6 Data collection 54
4.7 Data analysis 56
4.8 Significance of the study 56
4.9 Validity and reliability of the study 56
4.10 Potential limitations 57
4.11 Project outline 57
4.11.1 Time frame 57
4.11.2 Budget 57
4.12 References 58
4.13 Appendices 60
Section 5: Annexures 70

5.1 SASA green anaesthetic form 70

5.2 Epidural consent form 71

5.3 Upper limb block consent form 73

5.4 Ethics approval 75

5.2 Graduate studies approval 76

5.3 Turnitin report 77

5.4 Letter from supervisor accompanying Turnitin report 78

List of figures

Figure 1: Summary of methodology 35

List of tables

Table 1: Revised anaesthetic consent form ratings of the items and the CVI 38

Table 2: List of items that were not rated as content valid 42

Abbreviations

HPCSA	Health Professions Council of South Africa
AAGBI	Association of Anaesthetists of Great Britain and Ireland
SASA	South African Society of Anaesthesiologists
CVI	Content validity index
Wits	University of Witwatersrand

Statement

The Research Report consists of a literature review, draft article, study proposal and appendices. The study proposal is included for background reference and is not for examination.

The formatting of this Research Report complies with the University of the Witwatersrand's Style Guide for Theses, Dissertations and Research Reports. The formatting of the draft article may differ from the author guidelines of the South African Journal of Anaesthesia and Analgesia, the journal to which it is intended to be submitted, in order to comply with the university's style guide.

Section 1: Review of the literature

1.1 Introduction

Informed consent is fundamental to the way in which modern-day anaesthesia is practised. It is an important clinical entity as well as a medico-legal obligation to inform patients of the risks of anaesthesia. In this literature review the following aspects will be discussed: the history of informed consent, the concept of informed consent, the types of consent, the limitations to obtaining true informed consent, the need for a separate anaesthetic consent form, the ethical and legal obligations and the South African law pertaining to consent. The process of developing an instrument using Lynn's Model (1) of content validity will be discussed. This literature review will mainly focus on adult informed consent.

1.2 History of informed consent

It was not common practice in ancient Greece to have patients' participation in the decision-making of their medical treatment (2). It was believed that if physicians mentioned any risks about their treatment, it would jeopardise the trust that patients had in them. The Age of Enlightenment in the eighteenth century gave rise to the idea that patients were able to reason, however, it was still common practice to use deception to facilitate treatment (2). Paternalism was prominent in doctor-patient relationships.

As the concept of informed consent started gaining recognition, the English common law expanded its principles to the field of surgery around the twentieth century (2). The violation of a physician's duty toward his or her patient and an inadequate consent were paralleled with negligence. The patient's right to give or withhold permission for medical care was also introduced by English common law (3). It was after the 1947 War Crimes Trial that the first document, The Nuremberg Code recognised the importance of informed consent in research and it was extended to medical practice as a fundamental principle (4).

There have been several cases that have contributed to the development of informed consent as it is known today. A few landmark cases will be highlighted. In the 1914 case of Schloendorff versus Society of New York Hospital (5), Justice Benjamin Cardozo stated that "every human being of adult years in sound mind

has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits a battery for which he is liable in damages". Secondly, the 1957 case of Salgo versus Leland Stanford Jr University Board of Trustees (6), where a physician failed to inform his patient of possible complications of a translumbar aortography that left him paralysed after the procedure. It was due to this case that the term informed consent was first introduced in an American court and it became a legal requirement for all physicians to explain the risks and benefits of the planned procedure to the patient (6,7).

At the same time, in England, the case of Bolam versus Friern Hospital Management Committee (8) introduced the Bolam principle, which is a way of determining the amount of information that would be considered as negligence by the physician (8). In this case, Bolam, the plaintiff, claimed not having been informed about possible complications during electroconvulsive therapy where he sustained multiple fractures during the procedure. It was concluded from this case that a doctor could not be found guilty of negligence if they acted in accordance with a practice that is accepted as a set standard by a reasonable medical body (8). The physicians involved in this case were not found to be negligent as they provided the patient with the same information about complications that physicians in similar situations would have provided.

In 1993, the Bolam principle was rejected by the Australian High Court following the Rogers versus Whitaker case (9), where Dr Rogers failed to warn Whitaker of the potential risks of becoming blind after her eye surgery. The Bolam principle was replaced by the concept of material risk, which is defined as "a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is, or should reasonably be aware that the particular patient if warned of the risk, would be likely to attach significance to it" (7). This set the precedence for the movement towards a patientcentred approach, which aimed to preserve individual autonomy.

Informed consent received attention in South Africa in 1976, in the case of Richter versus Estate Hammann (10) but it was only introduced into South African law 18 years later, following the case of Castell versus De Greef in 1994 (11). This was the landmark case that gave informed consent the legal platform from which to develop. The case involved a patient who sued the plastic surgeon after her

prophylactic double mastectomy and simultaneous breast reconstruction and flap procedure. It was argued that the plastic surgeon had not disclosed the risks associated with the mastectomy and that if the patient had known of the material risks associated with the procedure she would not have proceeded with the surgery (11). The case highlighted that for consent to be considered valid, the consenting party must have been made aware of, and therefore appreciated and understood the nature and extent of the harm or risk associated with the procedure.

1.3 The concept of informed consent

Informed consent is defined by the American Medical Association (12) as "communication between a patient and physician resulting in the patient's authorization or agreement to undergo a specific medical intervention". The use of informed consent is an avenue that promotes respect for autonomy (13). The moral foundation of autonomy is based on the three elements of consent, as described by Beauchamp and Childress (14), which makes it a legally binding document. The preservation of patients' capacity to make autonomous decisions throughout their medical treatment is beneficial for patient satisfaction and is associated with good medical outcomes (15).

Beauchamp and Childress (14) distinguish three elements in the process of informed consent. The first being the threshold element, which encompasses individuals making autonomous decisions voluntarily as well as assessing patients' decision-making capacity. The second element is the informational element which encompasses full disclosure of material risks, benefits and alternatives. This element also allows the physicians to recommend a plan to a patient while ensuring that patients have an adequate understanding of the information given. The last element is the consent element, which involves the patient giving authorisation of his or her autonomous decision (14). The three elements will be briefly discussed.

Threshold element

The threshold element illustrates patients' decision-making capacity and voluntariness. The premise of autonomy is that one needs to have the capacity to make decisions (16). The word autonomy dates back to Ancient Greek and means

self-rule. Autonomy is “the capacity to think, decide, and act on the basis of such thought and decision freely and independently and without, as it says in the British passport, let or hindrance”(17). It ensures the decisions of adults who have decision-making capacity are respected (18). Three conditions need to be fulfilled for an action to be deemed autonomous, those with capacity need to display intention, complete understanding and the absence of controlling influences on their choice (18,19).

Capacity is determined by two components, age and decisional capacity (20). The age component is determined by legislation, where the law confers certain rights and obligations at various stages in their lives. In South Africa, the age where full legal capacity is realised is 18 years. At this age and older, people are assumed to possess the decisional capacity to make their own choices, unless it is otherwise believed with good reasons “that they have a mental impairment that compromises their ability to make specific decisions” (20).

Children aged 12 years or older with sufficient maturity to understand the implications of the proposed treatment may give their own consent to treatment (21). For surgical procedures, a parent or guardian’s written assent is required (21). For children less than 12 years or more than 12 years who lack maturity, require consent of his or her parent or guardian (21). It is, however, reasonable to seek assent from a minor who is able “to understand the benefits, risks, social and other implications of the treatment” (21).

Decisional capacity is an important component of the capacity to consent and encompasses two principles that need to be considered when obtaining consent. The fact that adults are presumed to be competent to make decisions, requires that for one to intervene without their consent, one needs to be satisfied that they lack the capacity to make a particular decision (20,22). In the case of minors, a general presumption is that they lack the capacity to make decisions, therefore one needs to be satisfied that they have sufficient maturity to make a particular decision before intervening.

Decisional capacity is defined as “the capacity to make decisions in light of information about the relevant risks, benefits and consequences of the proposed intervention” (20,22). It includes the ability to comprehend relevant information, appreciate the consequences and reason regarding treatment (20). Determining

whether an adult has the capacity to make decisions can often prove to be challenging for the physician.

An adult is assessed as having compromised decisional capacity if, at the time a decision needs to be made, he or she is unable to either make the decision for him or herself or to communicate his or her decision on the matter (23). The patient is expected to understand or retain information to make an informed decision based on the information given to them (23). Equally, an adult should not be regarded as lacking capacity if he or she is able to understand the information in simple language, or makes a decision which would not be made by a reasonable person (23). Lastly, all measures should be taken to enable communication of the patient's decision (23).

True autonomy may not always be achieved in all instances. One's decisionmaking capacity can be compromised either temporarily or permanently and may fluctuate over time (24). Some of these scenarios may be apparent, for example, a patient with dementia or someone who is unconscious (24). There are, however, a few instances where it may be more difficult to assess the degree of patient autonomy and decisional capacity. In the case of children, for example, where they possess independent thoughts but only become autonomous above a certain age when they are deemed to have decision-making capacity comparable to an adult. Similarly, one may still be able to retain the capacity to consent despite having a mental illness (24). The Mental Health Care Act 17 of 2002 (25) stipulates that involuntary and assisted mental health care users do not lose their right to treatment for illnesses other than mental illnesses. A surrogate will be appointed by the court to consent on the patient's behalf if the patient is deemed "incapable of consenting to treatment or an operation due to mental illness or intellectual disability" (25). It is thus important to assess cases of possible compromise of capacity on individual merit.

There are a few areas in anaesthesia practice that may jeopardise patient autonomy and have the potential to invalidate consent. Firstly, a patient in labour, for example, who may be in severe pain may agree to any form of pain relief, without understanding fully the risks involved in the pain-relieving treatment, for example, an epidural (24). Secondly, patients suffering from chronic pain may be dependent on an anaesthesia intervention and thus may overlook any risks involved in treatment (24). Lastly, opioids or sedatives can affect patients' capacity to make decisions (26).

A patient who is assessed as lacking decisional capacity requires someone else to make decisions about their medical treatment. This can be in the form of an advance directive, where the patient has previously appointed an individual to act as his or her proxy should the situation arise (20). In the absence of an advance directive, an individual will be appointed to make decisions on the patient's behalf. The surrogates are appointed in order of superiority as follows: a person authorised by law or a court order, the patient's spouse or partner, parent, grandparent, adult child and lastly brother or sister (20,22). The appointed individual is given the responsibility to make an informed decision on behalf of the patient, on condition that they are given sufficient information. The physician responsible for the patient will only decide how to proceed, using the "best interest" principle, should none of the above surrogates exist or cannot be contacted.

The best interest principle is applied either, if there is a difference between the physician's and the proxy's opinions about what the best medical treatment for the incapacitated patient is or if there are no surrogates available (20,27). The principle assists the physician to choose an option a reasonable person would choose in a similar situation. The physician needs to be cognisant of a number of factors that may influence this decision. To fulfil the best interest principle, the different treatment options should be considered in conjunction with the patient's preferences, if previously expressed, in an advance directive or to a third party such as the patient's partner (20,27). The patient's culture, religion and employment should also be considered (20,27). The option that least restricts the patient's future choices should be regarded as representing the patient's best interest. In the case of an emergency, the physician may intervene, under the terms of the National Health Act 61 of 2003 (22), "to prevent either death or irreversible damage to the patient's health, provided the patient had not 'expressly, impliedly or by conduct' refused such treatment".

The concept of voluntariness is influenced by several factors. It is a pre-requisite that a patient freely volunteers to give his or her consent, which may not always be possible as their readiness may be influenced by factors that hinder their decision (27). Influences can be from society, family, medical illness, anxiety, emotional stress and the clinician (28).

Information element

The information element ensures the disclosure of the material risk of the proposed procedure to the patient (14). Physicians can make recommendations towards a plan during this step and provide information about all alternative treatments available, including their risks (14). Lastly, the patient's understanding of the procedure being offered should be established (14).

It remains a challenge to quantify what constitutes adequate information. The National Health Act 61 of 2003 (22) and the Health Professions Council of South Africa (HPCSA) (27) outline the information that should be included in the informed consent process and aim to uplift patients' rights as set in the Constitution of the Republic of South Africa (29) and the National Patients' Health Charter (30). The statutory guidelines on the information that should be explained to patients will be discussed in Section 1.10.

Consent element

The last element, the consent element, is where the patient authorises and consents to a plan (14). Acquiring consent should not be seen as an isolated event, instead, it should be treated as an ongoing process. In most cases, the consent process starts in the surgical outpatient department. This allows the patient to think about the treatment options available and be given the opportunity to ask questions. According to the Medical Protection Society (20), there is no set time frame on consent taken in advance but it is good practice to give patients as much time as possible to come to a decision before consenting to treatment.

The physician providing the proposed treatment or procedure should be the person taking consent. If this is not possible, a physician who is qualified and equipped with sufficient knowledge of the risks of the proposed treatment can be assigned (20). It, however, remains the primary physician's responsibility to ensure that their patients have been given adequate information to make an informed decision (20).

The process of informed consent may not always result in the patient consenting to the procedure, as the patient has the right to refuse treatment. The concept of informed consent applies equally to refusal of treatment. Informed consent would be meaningless if the patient's right to refuse treatment is not protected (16,20).

Without the right of refusal, the consent process would merely demonstrate a paternalistic approach, where the physician acquires his will. The physician, however, may not coerce a patient into consenting to treatment nor can he or she override a patient's refusal if the patient is assessed to having decisional capacity (20). The physician has a moral and ethical duty, as stated in the National Health Act 61 of 2003 (22) and by the HPCSA (27), to explain to the patient the consequences of such a refusal. Patients also have the right to withdraw consent at any time during a treatment and the procedure should be stopped as soon as it is safe to do so (20).

1.4 Types of consent

The Association of Anaesthetists of Great Britain and Ireland (AAGBI) (28) distinguishes consent as either being implied or expressed. Much of what anaesthetists do in the clinical setting is consent that is merely implied by a patient. Implied consent is a passive process that does not need any formal documentation, for example, attaching monitoring, putting up a drip or taking a history. Implied consent is normally used for less intrusive interventions and patient's inaction is interpreted as consent (3).

Express consent is needed for any procedure that puts a patient at material risk (28). One should obtain express consent for procedures that are more invasive (3). Verbal consent is an example of express consent. It is consent that is given by a patient verbally without the need to sign a formal document. Written consent is essentially an extension of verbal consent, which serves as a legal document. Written consent should be obtained in the following situations; "the treatment or procedure is complex or involves significant risks and/or side effects; providing clinical care is not the primary purpose of the investigation or examination; there may be significant consequences to the patient's employment, social or personal life and; the treatment is part of a research programme" (20,27). Written consent is merely proof that a discussion has taken place, but not what was discussed. It is thus paramount that details of the discussion are documented in the patient's medical records (20,24).

1.5 Limitations on obtaining true informed consent

The rationale behind informed consent has merit in both clinical medicine and clinical research. The question does, however, come in, whether the purpose of informed consent is fulfilled at all times. Three authors (31–33), concluded that the limitations associated with informed consent can be attributed to many factors including the "sexual, cultural and socioeconomic differences in decision-making, and the difficulties associated with assessing capacity and voluntariness" and thus the aim to protect individual autonomy is often not met. Despite the paradigm shift away from paternalism, patients may still encourage this approach by entrusting their doctors to make medical decisions for them, as shown in a study, where 69% of patients did not read the consent form before signing (34).

Obtaining true informed consent can often be impractical considering the time constraints that are faced within a health system that is saturated and pressured to provide service delivery (24). There is often a moral trade-off between ethical obligations for consent and what is possible practically (24).

1.6 Need for a separate anaesthetic consent

The use and usefulness of a separate consent form for anaesthesia has been a subject of ongoing debate (35). Arguments that are in favour of a separate anaesthetic consent form believe that anaesthesia is unique in its nature, purpose and complications much like any surgical speciality (24,35). Rampersad et al (35) concluded that having a separate anaesthetic consent improved patients' understanding of the whole anaesthetic process. The same study showed that common side effects and complications were better understood. White (36) suggests that a separate anaesthetic consent form could act as a reminder or prompt the anaesthetist to have a discussion with the patient.

There have been several criticisms against having a separate anaesthetic consent form. The AAGBI (28) recommends that a separate written consent form for anaesthesia is not required if it is to facilitate another procedure. The rationale behind this is that the act of obtaining consent is more important than a signature on a consent form. The association believe that a written consent form does not necessarily "validate or invalidate the consent" but is mere "evidence that a consent process has been undertaken" (28). They do, however, suggest that there

should be some form of documentation in the patient's records of what was discussed verbally with the patient (28). Secondly, that consent forms are often too complex for patients to understand and that most patients sign consent without fully understanding the implications (34,37). Lastly, it appeared that consent forms were created to primarily protect the institution and not aid in patients' decisionmaking (38).

A separate consent form would make sense as it would prove to be beneficial for the patient and provide legal protection for the anaesthetist (39). However, despite the legal requirement to obtain consent, this topic remains contentious among anaesthetists.

1.7 Ethical and legal considerations of informed consent

The concept of informed consent is influenced by both a legal and moral component (40). This takes into account the welfare of both the patient and the practitioner. The hallmark of the ethical aspect of informed consent is based on the fundamental principles of autonomy, non-maleficence, beneficence and justice, which determine right and acceptable conduct (40).

Autonomy is the concept of a person who can think, decide and act based on such thought, independently and without hindrance (19). An autonomous patient should have the capacity to make an informed decision with the information presented by the physician, free of coercion. The practitioner has an ethical obligation towards a patient to respect their autonomy and to make decisions that are in the patient's best interest. Consent is thus used as a legal instrument to protect one's autonomy. An autonomous patient can, therefore, decide and control what happens to his or her body (19).

Non-maleficence and beneficence are two principles that are closely linked to one another. The principle of non-maleficence holds that there is a requirement not to inflict harm on others. It is closely associated with the maxim *primum non nocere* (first do no harm) (18). Beneficence looks at the duty to act for the benefit of others (18). These two ethical principles need to continually be balanced against one another as there are instances where the benefit of the treatment may outweigh the potential harm (18,40).

The principle of justice is divided into two major categories: procedural and distributive (41). Procedural justice ensures that patients are all treated fairly and equally (41). Distributive justice relates to the equal allocation of benefits, risks, costs and resources among all patients unless there is a valid reason to discriminate (18,41).

The ethical and legal considerations of informed consent mirror one another in that one can either refuse or accept a treatment (28). The once-popular concept of battery and assault (3) where one was charged for touching a patient without his or her consent was superseded by the theory of negligence. A claim of negligence against a physician refers to insufficient information given to a patient regarding medical treatment that would have lead him or her to refuse treatment, even if the outcome would otherwise have been unchanged (3). It is the sole responsibility of the practitioner who is going to perform the procedure to ensure that appropriate informed consent has been taken to avoid a claim of battery or negligence (24).

The informed consent document is merely proof that a discussion took place but a practitioner can still be found guilty of negligence (24). The process of consent is swayed by the medical profession but the fundamentals lie in the fact that it is a requirement by law to obtain consent (22).

1.8 Legislation and regulations regarding informed consent in South Africa

Informed consent in South Africa is informed by the Constitution of the Republic of South Africa 108 of 1996 (29), the National Health Act 61 of 2003 (22), case laws, the HPCSA Guidelines (27) and the National Patients' Health Charter (30) and will be briefly discussed.

The Constitution of the Republic of South Africa 108 of 1996

The Constitution of the Republic of South Africa (29) is the supreme law of the land and serves to protect its citizens by upholding human dignity, equality and freedom. Informed consent encompasses a number of rights enshrined in the Bill of Rights of the Constitution of the Republic of South Africa. These rights include: the right to bodily and psychological integrity (Section 12) (29); the right to freedom of religion, belief and opinion (Section 15) (29); and the right of access to information (Section 32) (29).

The National Health Act 61 of 2003

Informed consent encompasses the rights protected in the Constitution of the Republic of South Africa, which allows the legislature to legislate on the issues involving informed consent. The National Health Act 61 of 2003 (22) addresses informed consent in Sections 6-8 of the Act.

The Act (22) states that informed consent needs to be obtained for medical intervention but does not explicitly stipulate that separate consent should be obtained for anaesthesia. The Act (22) specifies certain aspects regarding informed consent that the anaesthetist needs to be cognisant of when obtaining consent from a patient. Firstly, the patient has the right to participate in decisions affecting their health and treatment and the anaesthetist must take all reasonable steps to obtain informed consent from the patient. Secondly, the anaesthetist, using language that the patient understands must inform the patient of their health status, the range of diagnostic procedures and treatment options available and the benefits, risks, costs and consequences generally associated with each option. Thirdly, the anaesthetist needs to inform the patient of the right to refuse an intervention and explain the implications, risks and obligations of such refusal. Lastly, it requires the anaesthetist to share relevant information with patients who lack the capacity to make decisions “unless the disclosure of such information would be contrary to the user’s best interests” (22).

Case laws

The case of Castell versus De Greef (11) was mentioned in Section 1.2, which was the first recognised case involving informed consent in South Africa. In this case, the judge supports the criteria of material risk as that described in the Rogers versus Whitaker (9) case in Australia but specifically states “the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it”. The South African case laws went a step further than the legislation to say that patients not only need to be given knowledge but that they need to have understood the knowledge given. Furthermore, the Lourens versus Oldwange case (42) case shed light on what percentage of a risk a reasonable doctor needs to disclose to a patient.

The Health Professions Council of South Africa

The HPCSA is a body that sanctions the right and privilege of medical professions. The HPCSA adhere to the principles set out in the Constitution on the moral and ethical duties that practitioners have on society as well as the legal obligations.

The HPCSA Guidelines Booklet 4 titled “Seeking informed consent: the ethical considerations” (27), stipulates that patients have the right to information about their condition and the available treatment options that are available to them. The amount of information provided to patients, however, should be individualised as not one case is identical. It is thus essential that the physician conducting the interview should seek to understand and quantify how much information a patient wants to know about his or her medical illness or treatment.

The HPCSA guidelines (27) are set in accordance with the National Health Act (22) and it incorporates the patients right to:

- “information about any condition or disease from which they are suffering;
- details of the diagnosis and prognosis, and the likely prognosis if the condition is left untreated;
- uncertainties about the diagnosis, including options for further investigation before treatment;
- options for treatment or management of the condition, including the option not to treat as well as the likely benefits and the probabilities of success of each option;
- the purpose of a proposed investigation or treatment;
- the name of the doctor who will have overall responsibility for the treatment;
- whether students will be involved in an investigation or treatment;
- change their minds about a decision at any time;
- seek a second opinion and
- details of costs or charges which the patient may have to meet” (27).

It is the health care practitioners responsibility to do their best to find out about patients' individual needs and priorities of their specific beliefs, culture, occupation or any other information that may influence their decision (27). Section 12 of the Guidelines (27), stipulates that health care practitioners have to fulfil their legal obligation of detailing what was discussed with the patient and record it either in

the patient's case notes or on the consent form. It does not, however, mention a separate consent form for anaesthesia as a legal requirement.

The National Patients' Health Charter of 2008

The National Patients' Rights Charter (30) was initiated by the Minister of Health and is supported by the HPCSA. The charter states that for patients to make a decision about their health, they have the right to full disclosure about the nature of their illness, the proposed treatment, the risks associated and the costs involved (30).

1.9 South African Society of Anaesthesiologists and informed consent

The South African Society of Anaesthesiologists (SASA) was founded in 1943 and is a member-based association that is committed to doctors who practise anaesthesia at both an academic and clinical level.

The 2018 SASA Practice Guidelines (43) include the following regarding informed consent:

- it is a requirement to obtain informed consent;
- SASA advocates that one uses a policy to guide the process for informed consent;
- a separate anaesthetic consent form should be available to explain risks
- all information on the nature of the anaesthetic planned should be disclosed to the patient, including the fee estimate;
- logistics regarding the scheduled procedure have to be confirmed by the anaesthetist;
- the patient's fears be addressed;
- explanation of the common and relevant risks associated with the anaesthetic procedure to the patient and/or family member. It is essential that one does this with caution to avoid unnecessary anxiety regarding rare complications for example, but it is acceptable to inform patients about catastrophic outcomes such as death and paralysis;
- patients should have the freedom to ask questions and be given honest answers. The manner in which one responds to questions should be

individualised as a patient's level of education and medical background may differ;

- an information sheet should be available with information on fasting, anaesthesia and pain relief before hospital admission;
- patients are entitled to ask about what qualifications and experience the anaesthetist holds and should be informed (43).

SASA green anaesthetic form

SASA has made available to its members, SASA refers to the consent form as the green anaesthetic form (Annexure 1) which is a generic consent form for all types of anaesthesia, an epidural consent form (Annexure 2) and an upper limb block consent form (Annexure 3).

The green anaesthetic consent form is divided into four different sections, namely A-D. Section A is a declaration agreement between the anaesthesiologist and patient, section B requests the patient details, the person responsible for the account fills out section C and section D is a list of medical conditions that patients are required to tick as yes or no. There is also a section pertaining to the anaesthetic record but this is beyond the scope of this research report and will not be discussed.

The green anaesthetic form does not comply with certain requirements set by law to deem a consent as valid. The law requires that patients' health status is disclosed. Section D provides a list of conditions and the patient is expected to tick those that he or she suffers from and allows more detail to be provided.

Healthcare practitioners are expected to explain consequences, benefits and risks that are generally associated with each treatment option (22). SASA (43) require that all information, as well as common and relevant risks associated with the planned anaesthetic, is explained to the patient. Despite SASA's requirement, the green anaesthetic form does not show any evidence of this.

The green anaesthetic form appears to be tailored mainly toward paying patients which are most frequently encountered in the private sector. This is supported by the details regarding payment, International Classification of Diseases codes and medical aid details. It does, however, comply legally with disclosing the costs that patients will incur.

The upper limb block consent and the epidural consent, however, are more detailed and provide more information regarding the procedure as well as the risks and complications. There is, however, a need to develop an anaesthetic consent form that encompasses all aspects of anaesthesia care on one consent form.

In the South African setting, particularly in the public healthcare in the Johannesburg Academic Hospitals, the extent of evidence of anaesthetic consent lies within a one-line item on the surgical consent form. A patient who consents to an operation would imply that he or she consents to anaesthesia whether it be under general anaesthesia or another form of anaesthesia. The current SASA green anaesthetic form does not fulfil all the requirements that are mandatory to be recorded by law to deem a consent valid. For these reasons, a need to develop and validate an anaesthetic consent form for the public sector arose.

1.10 Development and validation of an anaesthetic consent form

Validity refers to the degree to which a measurement represents a true value (44).

The quantification of the content validity of an instrument can be achieved using, among others, the content validity index (CVI) (1). Lynn's Model (1) will be used to achieve content validity in this study. Lynn's Model (1) was first described in 1986 and remains a widely used method of obtaining content validity as recommended by Polit and Beck (45) in 2006. It is a two-stage process that consists of a Development Stage and a Judgement/Quantification Stage. This will be used to determine the content validity of the anaesthetic consent form that will be developed.

The Development Stage of Lynn's Model (1) consists of three steps: domain identification, item generation and instrument formation. Domain identification will be done by an extensive review of the literature for what should be included in an anaesthetic consent form. This step will be followed by generating a provisional anaesthetic consent form (item generation). Lastly, a group discussion will be held to debate and refine the provisional anaesthetic consent form in order to develop the revised anaesthetic consent form (instrument formation).

The Judgement/Quantification stage of Lynn's Model (1) has two steps. The first is the assertion by a specific number of experts that the items of the list are content valid. The second step is the assertion that the entire list is content valid (1).

According to Lynn (1), the number of experts chosen in the two stages is arbitrary, as it depends on how many experts are accessible, available and willing. The author suggests that a minimum of five experts would provide a sufficient level of control for chance agreement and that the maximum number of participants has not been established but does not usually exceed 10 (1).

Lynn (1) makes use of a cumulative binomial distribution to determine the proportion of experts needed to rate an item as valid. The cumulative binomial distribution is published as standard norms to establish a content validity beyond the 0.05 level of significance (1). The CVI is derived from rating items using a Likert rating scale. A four-point rating scale is preferable because it does not include the ambivalent middle rating common in odd number rating scales. The CVI of all the items on the consent form will be determined. The CVI for the entire anaesthetic consent form can be derived from the proportion of items judged as content valid.

1.11 Summary

Treating competent patients without their valid consent is a violation of their constitutional rights (20). The attainment of informed consent from a patient is a right protected by both the Constitution (29) and National Health Act 61 of 2003 (22) of South Africa. The South African law, however, specifies consent for medical intervention as a whole and does not view anaesthesia as a separate discipline. In the South African public sector, the practice of obtaining informed consent for anaesthesia in the form of written consent is not standardised despite it being a statutory requirement.

1.12 References

1. Lynn, M. Determination and quantification of content validity. Nurs Res. 1986;35(6):382–5. doi:10.1097/00006199-198611000-00017.

2. Murray PM. The history of informed consent. Iowa Orthop J. 1990;10:104–9.

3. Wolverton S, Kapp M. Informed consent and risk management. In: Wolverton S, Wu J (eds) Comprehensive dermatologic drug therapy. 3rd Edition. Edinburgh, UK: Saunders Elsevier; 2013. p. 766–70.

4. Weindling P. Nazi medicine and the Nuremberg Trials: From medical warcrimes to informed consent. London, UK: Palgrave Macmillan; 2004. p. 93-125

5. Schloendorff v. Society of New York Hosp., 105 N.E. 92, 93 (N.Y. 1914) [Internet]. [cited 2020 Jul 8]. Available from: https://biotech.law.lsu.edu/cases/consent/schoendorff.htm

6. Salgo v. Leland Stanford Etc. Bd. Trustees, 317 P.2d 170, 154 Cal. App. 2d 560 [Internet]. CourtListener. 1957 [cited 2020 Jun 22]. Available from: https://www.courtlistener.com/opinion/2619445/salgo-v-leland-stanford-etc-bdtrustees/

7. Braun AR, Skene L, Merry AF. Informed consent for anaesthesia in Australia and New Zealand. Anaesth Intensive Care. 2010 Sep;38(5):809–22. doi:10.1177/0310057X1003800504

8. Bolam v Friern Hospital Management Committee [1957] 1 WLR 583 [Internet]. [cited 2020 Jun 24]. Available from: https://www.lawteacher.net/cases/bolam-vfriern-hospital-management.php

9. Australian High Court. Rogers versus Whitaker. Aust Law J. 1993 Jan;67(1):47–55.

10. South African Supreme Court. Richeter versus Estate Hammann. S Afr Law Rep. 1976;(3):226–35.

11. South African Supreme Court. Castell versus De Greef. S Afr Law Rep. 1994;1994(4):408–41.

12. American Medical Association. Informed consent [Internet]. [cited 2018 Nov 21]. Available from: https://www.ama-assn.org/delivering-care/informed-consent

13. Young R. Informed consent and patient autonomy. In: Kuhse, H, Singer, P (eds) A companion to bioethics. Second Edition. Malden, MA: Blackwell Publishing Ltd; 2009. p. 530–40.

14. Beauchamp L, Childress J. Principles of Biomedical Ethics. Fifth Edition. New York, NY: Oxford University Press; 2001.

15. Waisel DB, Truog RD. The benefits of the explanation of the risks of anesthesia in the day surgery patient. J Clin Anesth. 1995 May 1;7(3):200–4. doi:10.1016/0952-8180(94)00047-8

16. Van Norman GA, Rosenbaum SH. Ethical Aspects of Anesthesia Care. In: Millers Anaesthesia. Eighth Edition. Philadelphia, PA: Elsevier Saunders; 2014. p. 232–50.

17. Gillon R. Autonomy and the principle of respect for autonomy. Br Med J Clin Res Ed [Internet]. 1985 Jun 15 [cited 2018 Nov 19];290(6484):1806–8. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1415948/

18. Jahn WT. The 4 basic ethical principles that apply to forensic activities are respect for autonomy, beneficence, nonmaleficence, and justice. J Chiropr Med. 2011 Sep;10(3):225–6. doi:10.1016/j.jcm.2011.08.004

19. Gillon R. Autonomy and the principle of respect for autonomy. Br Med J Clin Res Ed. 1985 Jun 15;290(6484):1806–8.

20. Medical Protection Society. Advice booklets: Consent to medical treatment in South Africa [Internet]. 2012 [cited 2018 Nov 21]. Available from: https://www.medicalprotection.org/southafrica/advice-booklets/consent-to-medicaltreatment-in-south-africa-an-mps-guide/capacity

21. Republic of South Africa. Children's Act No. 38 of 2005.

22. Republic of South Africa. The National Health Act 61 of 2003.

23. South African Law Reform Commission, Discussion Paper 105. Assisted decision-making: Adults with impaired decision-making capacity [Internet].

2004 [cited 2020 Jul 9]. Available from: https://www.justice.gov.za/salrc/reports/r_pr122-Assisted-Decision-Making-Dec2015.pdf

24. White SM, Baldwin TJ. Consent for anaesthesia. Anaesthesia. 2003;58(8):760–74. doi:10.1046/j.1365-2044.2003.03202.x

25. Republic of South Africa. Mental Health Care Act 17 of 2002.

26. Kopp VJ. Communication with patients before anesthesia and obtention of preanesthetic consent. Curr Opin Anaesthesiol. 2002 Apr;15(2):251–5. doi:10.1097/00001503-200204000-00018

27. Health Professions Council of South Africa. Guidelines for good practice in the health care professions. Seeking patients' informed consent: The ethical considerations. Booklet 4 [Internet]. Pretoria. 2016 [cited 2019 May 30]. Available from: https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf

28. Yentis SM, Hartle AJ, Barker IR, Barker P, Bogod DG, Clutton-Brock TH, et al. AAGBI: Consent for anaesthesia 2017: Association of Anaesthetists of Great Britain and Ireland. Anaesthesia. 2017 Jan;72(1):93–105. doi:10.1111/anae.13762

29. Republic of South Africa. Constitution of the Republic of South Africa Nr 108 of 1996.

30. Health Professions Council of South Africa. Guidelines for good practice in the health care professions. National patients' rights charter. Booklet 3 [Internet]. Pretoria. 2016 [cited 2020 Jul 9]. Available from: https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf

31. Veatch RM. Abandoning Informed Consent. Hastings Cent Rep. 1995;25(2):5–12. doi:10.2307/3562859

32. Jones M. Informed consent and other fairy stories. Med Law Rev. 1999 Jun 1;7(2):103–34. doi:10.1093/medlaw/7.2.103

33. O'Neill O. Paternalism and partial autonomy. J Med Ethics. 1984 Dec 1;10(4):173–8. doi:10.1136/jme.10.4.173

34. Lavelle-Jones C, Byrne DJ, Rice P, Cuschieri A. Factors affecting quality of informed consent. BMJ. 1993 Apr 3;306(6882):885–90. doi:10.1136/bmj.306.6882.885

35. Rampersad K, Chen D, Hariharan S. Efficacy of a separate informed consent for anesthesia services: A prospective study from the Caribbean. J Anaesthesiol Clin Pharmacol. 2016;32(1):18–24. doi:10.4103/0970-9185.173364

36. White SM. Consent for anaesthesia. J Med Ethics. 2004 Jun 1;30(3):286–90. doi:10.1136/jme.2002.001610

37. Jubelirer SJ. Level of reading difficulty in educational pamphlets and informed consent documents for cancer patients. W V Med J. 1991 Dec;87(12):554–7.

38. Bottrell MM, Alpert H, Fischbach RL, Emanuel LL. Hospital informed consent for procedure forms: facilitating quality patient-physician interaction. Arch Surg Chic Ill 1960. 2000 Jan;135(1):26–33. doi:10.1001/archsurg.135.1.26

39. Marco AP. Informed onsent for surgical anesthesia care: Has the time come for separate consent? Anesth Analg. 2010 Feb;110(2):280. doi:10.1213/ANE.0b013e3181c30f8e

40. Nanda A, Nasser M. Informed consent and medico legal aspects of neurosurgery. In: Complications in Neurosurgery. 1st Edition. Edinburgh, UK: Elsevier; 2019. p. 6–9.

41. Morrison, Furlong E, Summers J. Principle of healthcare ethics. In: Health care ethics. Fourth Edition. Burlington, MA: Jones & Bartlett Learning; 2019. p. 47–63.

42. South African Supreme Court of Appeal. Louwrens versus Oldwage 2006 (2) SA 161 (SCA).

43. South African Society of Anaesthesiologists. Practice Guidelines Revision 2018 [Internet]. 2018 [cited 2019 May 30]. Available from: https://sasaapi.sasaweb.com/Document/SAJAA(V24N1)2061SASAPracticeGuidelines_V12_636803016948256880.pdf

44. Botma Y, Greef M. Research in health sciences. Cape Town, SA: Heinemann; 2010.

45. Polit DF, Beck CT. The content validity index: are you sure you know what's being reported? Critique and recommendations. Res Nurs Health. 2006 Oct;29(5):489–97. doi:10.1002/nur.20147

Section 2: Author's guidelines

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The following are sample references:

1. Jun BC, Song SW, Park CS, Lee DH, Cho KJ, Cho JH. The analysis of maxillary sinus aeration according to aging process: volume assessment by 3dimensional reconstruction by high-resolutional CT scanning. Otolaryngol Head Neck Surg. 2005 Mar;132(3):429-34.
2. Polgreen PM, Diekema DJ, Vandeberg J, Wiblin RT, Chen YY, David S, et al. Risk factors for groin wound infection after femoral artery catheterization: a case-control study. Infect Control Hosp Epidemiol [Internet]. 2006 Jan [cited 2007 Jan 5];27(1):34-7. Available from: http://www.journals.uchicago.edu/ICHE/journal/issues/v27n1/2004069/2004069.web. pdf.

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4. All author details (Full names, Qualifications and affiliation) must be provided.
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6. There must be an abstract and keywords.
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8. It must be clear where every figure and table should be placed in the text. If possible, tables and figures must be placed in the text where appropriate. If too large or impractical, they may be featured at the end of the manuscript or uploaded as separate supplementary files.
9. All photographs must be at 300dpi and clearly marked according to the figure numbers in the text. (Figure 1, Table II, etc.)
10. All numbers below ten, without percentages or units, must be written in words.
11. Figure numbers: Arabic, table numbers: Roman

Section 3: Draft article

Development and validation of an anaesthetic consent form

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Key words: informed consent, Lynn's Model, content validity

Abstract

Background

Informed consent is an integral part of daily anaesthetic practice. It is an important clinical entity as well as a medico-legal obligation to inform patients of the risks of anaesthesia. The aim of this study was to develop and validate an anaesthetic consent form for surgery at the University of Witwatersrand affiliated hospitals.

Methods and results

A prospective, exploratory and instrumental design was used for the study. Purposive sampling was used in Lynn's two-stage Model of determination and quantification of content validity. The first stage, the Development Stage, involved an extensive review of the literature, which was followed by a peer group discussion. Local experts debated each item until 100% consensus was reached. The revised anaesthetic consent form consisted of 95 items. The Judgement/Quantification Stage involved 10 national experts using a four-point Likert scale for rating and validation. Items that were rated 3 or 4 were considered content valid. This resulted in 65 of 95 items being considered content valid. The revised anaesthetic consent form received a content validity index (CVI) of 0.68. Lynn suggests that for an instrument to be considered content valid, a minimum CVI of 0.8 should be obtained.

Conclusion

The CVI of the final instrument did not meet content validity requirements. However, the principle of informed consent remains important in good anaesthesia practice as it is an ethical and legal requirement to obtain before any procedure. Further research is required to develop the optimal anaesthesia consent form.

Introduction

Informed consent is fundamental to how modern-day anaesthesia is practised. In ancient Greece, it was not common practice to explain medical risks to patients as it was believed that it would decrease the trust they had in their physician's capability (1). Informed consent was first introduced to medical practice in the eighteenth century under the English common law, whereby patients gave or withheld permission to medical care (2). The 1947 Nuremberg Code recognised the importance of informed consent in research and it was extended to medical practice as a fundamental principle (3).

Informed consent was, however, only recognised by the courts after the 1957 case of Salgo versus Leland Stanford Jr. University Board of Trustees (4), where the plaintiff claimed that he was not informed about the risks associated with an aortogram, which left his lower limbs permanently paralysed. This landmark case was the beginning of the move away from a paternalistic approach to a more patient-centred relationship where patient autonomy became accepted in clinical practice (5,6).

Informed consent received attention in South Africa in 1976, in the case of Richter versus Estate Hammann (7) but was only introduced into South African law 18 years later, following the 1994 case of Castell versus De Greef (8). In this case, a medical practitioner was found guilty of not disclosing complications of necrosis and infection to a patient undergoing an elective prophylactic double mastectomy and simultaneous breast reconstruction and flap procedure.

In the South African setting, informed consent encompasses the rights enshrined in the Constitution (9), the supreme law of the land, which allows for legislation on the issues involving informed consent. The National Health Act 61 of 2003 (10) states that informed consent needs to be obtained for medical intervention but does not explicitly stipulate that separate consent should be obtained for anaesthesia. The Health Professions Council of South Africa (HPCSA) who govern the medical practice in South Africa has published guidelines (11) for obtaining informed consent that was derived from the National Health Act 61 of 2003 (10).

The current practice in South Africa regarding having a separate consent form for surgery and for anaesthesia differs and is not standardised in the public and

private sectors. Some institutions have one consent form and others have a separate consent form for surgery and anaesthesia. The South African Society of Anaesthesiologists (SASA) Practice Guidelines (12) suggest that it is a requirement to obtain separate informed consent for patients undergoing anaesthesia as the standard of care. Despite the recommendations being made, there is no evidence that this practice is standardised in South African public healthcare.

There is no separate consent form for anaesthesia at the hospitals affiliated to the Department of Anaesthesiology at the University of the Witwatersrand (Wits). The practice is verbal and consent is implied with a one-line item on the surgical consent form. This practice does not ensure patients' understanding of the risks, benefits, complications or the alternative anaesthetic techniques available. The aim of this study was to develop and validate an adult anaesthetic consent form for surgery at the Wits affiliated hospitals using Lynn's two-stage Model (13).

Methods and results

A prospective, exploratory and instrumental design was followed using Lynn's Model (13). The model is a two-stage process that consists of a Development Stage and a Judgement/Quantification Stage. Purposive sampling was used for both stages. The study population consisted of local and national experts. An expert was defined as an anaesthesiologist or other professional who is knowledgeable in the medico-legal field and has good standing in the healthcare community. The number of experts chosen in the two stages is arbitrary, according to Lynn (13), as it will depend on the number of experts that are accessible, available and willing to participate. A minimum of five experts provide a sufficient level to control for chance agreement and the maximum number of participants has not been established (13). A summary of the methodology is shown in Figure 1. Due to the study method, the method and results will be presented together for each stage.

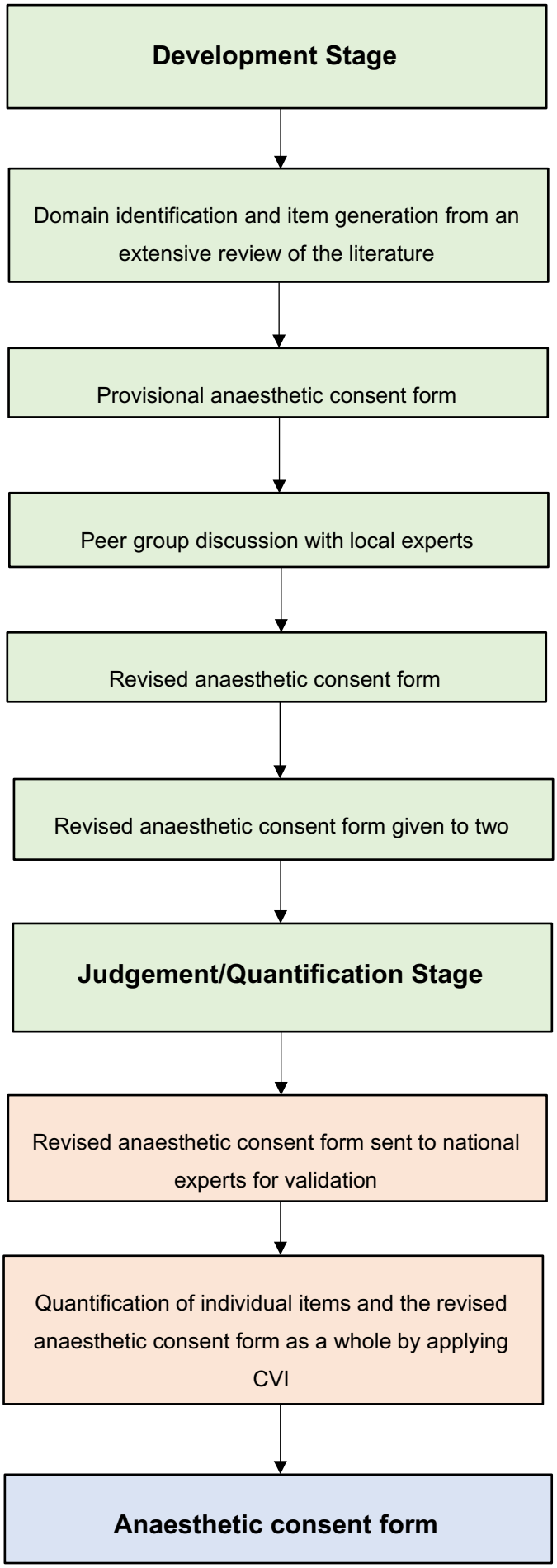

Development Stage
Domain identification and item generation from an extensive review of the literature
Provisional anaesthetic consent form
Peer group discussion with local experts
Revised anaesthetic consent form
Revised anaesthetic consent form given to two
Judgement/Quantification Stage
Revised anaesthetic consent form sent to national experts for validation
Quantification of individual items and the revised anaesthetic consent form as a whole by applying CVI
Anaesthetic consent form

Figure 1: Summary of methodology Stage 1: Development Stage

The Development Stage of Lynn's Model (13) consists of three steps: domain identification, item generation and instrument formation. Domain identification was done by an extensive review of the literature on what should be included in an anaesthetic consent form. This step was followed by generating a provisional anaesthetic consent form (item generation). The provisional anaesthetic consent form consisted of 10 domains and 87 items. Lastly, a peer group discussion was held to debate and refine the provisional anaesthetic consent form to develop the revised anaesthetic consent form (instrument formation).

Eleven local experts were identified and were sent an information letter, inviting them to participate in the study. The provisional anaesthetic consent form with preparation instructions was e-mailed to the five experts who accepted the invitation.

The peer group discussion was conducted in the Anaesthesiology Research Office and the attendees were asked to sign consent forms. Three experts work in the private sector and two in the public sector with all experts having more than 10 years of experience. The experts were tasked with refining the provisional anaesthetic consent form to improve the content validity of the instrument.

The peer group discussion was conducted by two authors (KSP and JS). The experts were expected to review and grade the items on the provisional anaesthetic consent form according to the following Likert scale by determining whether each item was:

- 1 = Not important information
- 2 = Useful information
- 3 = Important information
- 4 = Essential information.

Recommendations were made in the form of additions, refinements or removal of items**.** Data analysis was not required at this stage, as each item was debated until 100% consensus was achieved.

Changes were made to the provisional anaesthetic consent form according to the recommendations made during the peer group discussion in preparation for the

Judgement/Quantification Stage. The revised anaesthetic consent form consisted of 11 domains and 95 items. The revised anaesthetic consent form was sent to two participants to verify the changes made.

Stage 2: Judgement/Quantification Stage

The Judgement/Quantification stage of Lynn's Model has two steps (13). The first is the assertion by a specific number of experts that the items on the list are content valid. The second step is the assertion that the entire list is content valid (13).

Lynn (13) states that the quantification of content validity can be achieved using the content validity index (CVI). The CVI is derived from rating items using a Likert scale. A four-point rating scale is preferable because it does not include the ambivalent middle rating common in odd number rating scales. The same four-point Likert scale used in the Development Stage was used in this stage.

Thirteen national experts were identified and sent an e-mail inviting them to take part in this stage along with instructions and the revised anaesthetic consent form which was sent as a link to an anonymous Google Form. The local experts who took part in the Development Stage were excluded from this stage. The experts were asked to rate each item using the same four-point Likert scale used in the Development Stage. Ten national experts completed the Google Form. The national experts' characteristics were unknown due to the anonymity of the form.

Lynn (13) suggests that the proportion of experts whose endorsement is required to establish content validity for an instrument depends on the number of experts available. For this study 8 out of 10 (0.8) as suggested by Lynn (13) was taken as the acceptable number of experts required to deem an item content valid. Table 1, shows the 10 experts' ratings of the items with the corresponding CVIs.

Firstly, the CVI for each item will be determined by the proportion of experts who rated it as content valid with a rating of three or four on the rating scale. Secondly, the CVI of all the items on the consent form is determined. The CVI validity index for the entire consent form is the proportion of items judged as content valid.

Table 1: Revised anaesthetic consent form ratings of the items and the CVI

Patient details	1	2	3	4	CVI
Name and surname	0	0	0	10	1.0
Hospital number	1	1	1	7	0.8
Date of birth	1	0	0	9	0.9
Guardian/Proxy: Name and surname	0	1	0	10	1.0
Guardian/Proxy: Relationship	0	1	1	8	0.9
Guardian/Proxy: Contact number	1	1	1	7	0.8
Guardian/Proxy: ID number	2	0	1	7	0.8
Guardian/Proxy: Signature	1	0	1	8	0.9
Anaesthetist					
Name	0	1	0	9	0.9
Qualification	1	2	1	6	0.7
Rank (Community service officer, Medical officer, Registrar, Consultant)	2	3	2	3	0.5
Name of surgery/procedure	0	1	1	8	0.9
Date (consent obtained)	0	0	1	9	1.0
Types of anaesthesia recommended: (tick box)					
General anaesthesia	1	0	3	6	0.9
Spinal of epidural anaesthesia: with sedation, without sedation, with general anaesthetic	1	0	3	6	0.9
Regional nerve block: with sedation, without sedation, with general anaesthetic	1	0	3	6	0.9
Monitored anaesthesia care	1	0	3	6	0.9
Additional lines for monitoring					
Urine catheter: A pipe is placed in your urethra once you are unconscious. This will allow the anaesthetist to monitor how much urine you make during the surgery.	2	3	5	0	0.5
Nasogastric tube: A pipe is placed through your nose to your stomach. This will allow the anaesthetist to drain any excess air and stomach contents.	2	3	5	0	0.5
Arterial line: this is a special drip placed in your artery. It will allow your anaesthetist to monitor your blood pressure beat-to-beat.	1	1	2	6	0.8
Central venous catheter: This is a special drip that is placed in one of the major veins in your body. It will be done using an aseptic technique. It will be done either awake or asleep	1	0	3	6	0.9
Fibreoptic intubation: This will be done awake or asleep. It will depend on your anaesthetist's judgment. A scope with a camera	2	1	2	5	0.7

will be placed in your nostril this will help guide placement of a tube into your windpipe.					
Transoesophageal echo: this is a special ultrasound placed in your oesophagus once you are asleep. It will be used to monitor your heart during the surgery	1	3	2	4	0.6
General anaesthesia					
I will be rendered completely unconscious before the operation	1	1	1	7	0.8
I will not be aware of the events and will not feel any pain during the operation.	1	2	2	5	0.7
Drugs will be injected into my bloodstream and/or I will breathe in anaesthetic gas.	0	2	4	4	0.8
A breathing tube will be placed in my windpipe for this procedure.	0	1	4	5	0.9
Your anaesthetist will be with you during the entire procedure.	0	2	3	5	0.8
Common risks					
Bruising at the site of injections or intravenous lines	0	4	4	2	0.6
Nausea and vomiting – (1 in 5, 20%)	0	1	4	5	0.9
Sore or dry throat from the breathing tube, you may have difficulty speaking for a few hours	0	1	4	5	0.9
Headache	1	3	3	3	0.6
Blurred vision and dizziness	1	3	4	2	0.6
Difficulty passing urine	0	2	6	2	0.8
Less common risk					
Temporary muscle pain	0	3	4	3	0.7
Mild allergic reactions to drugs or blood products (itching or rash)	0	3	4	3	0.7
Uncommon risks					
Awareness under anaesthesia – 1:50 000	0	2	3	5	0.8
Damage to teeth or dental work, nose, lips or tongue – 1:1000	0	1	1	8	0.9
Skin injury due to equipment used during surgery	1	2	5	2	0.7
Nerve injury due to positioning required for surgery	1	2	3	4	0.7
Spillage of stomach contents into the lungs	1	0	3	6	0.9
Severe allergic reactions resulting in shock- 1:10 000 to 1:20 000	0	1	5	4	0.9
Chest infection (more common in patients with co-morbid conditions such as diabetes, heart disease and smoking)	1	0	4	5	0.9
Rare risks (More likely or more severe if you smoke, are overweight or have co-morbid conditions such as diabetes and heart disease)					

Malignant hyperthermia: Inherited muscle sensitivity to certain anaesthetic drugs. An uncontrollably high temperature with muscle rigidity.	3	4	2	1	0.3
Heart attack	1	3	3	3	0.6
Stroke	1	3	2	4	0.6
Pulmonary embolism – a clot in your lung (1:1000)	1	2	3	4	0.7
Obstruction in the breathing passages that cannot be readily controlled.	2	2	2	4	0.6
Hypoxia – a lack of oxygen that may result in brain damage or other organ failure	1	3	1	5	0.6
Death due to any cause – 1:100 000|	1	2	1	6	0.7
Spinal or epidural anaesthesia					
This type of anaesthesia causes temporary decreased or loss of feeling and/or movement to the lower part of your body	0	0	0	10	1.0
Local anaesthetic is injected through a needle or catheter placed either directly into the spinal canal or immediately outside the spinal canal	0	1	1	8	0.9
Common risks					
Headache	0	1	4	5	0.9
Muscle weakness in the anaesthetised limb(s)	0	1	4	5	0.9
Difficulty passing urine	0	1	4	5	0.9
Failed spinal: This is when the local anaesthetic doesn't work. You will be rendered unconscious and undergo general anaesthesia for the surgery.	0	0	3	7	1.0
High spinal: Local anaesthetic spread to a higher level. You will be rendered unconscious and undergo general anaesthesia for the surgery.	2	0	4	4	0.8
Uncommon risks					
Infection at the injection site	1	3	4	2	0.6
Bleeding at the injection site	0	2	5	3	0.8
Temporary backache	1	4	3	2	0.5
Bruising	2	4	2	2	0.4
Rare risks					
Nerves may be damaged resulting in long-term/permanent weakness, pain, numbness and paralysis	0	1	2	7	0.9
Spinal hematoma: clot next to spinal causing compression	0	1	2	7	0.9
Nerve blocks					
Local anaesthesia is injected near nerves	0	1	2	7	0.9

This will cause a temporary loss of feeling and/or movement of a specific limb or area	0	1	1	8	0.9
Common risks					
Weakness in your limb(s)	1	1	3	5	0.8
Uncommon risks					
Persistent numbness	0	1	4	5	0.9
Residual pain	0	1	6	3	0.9
Injury to blood vessels	0	3	5	2	0.7
Monitored anaesthesia care					
You will be rendered into a sleepy state either by a drug being injected into your bloodstream or breathed into your lungs.	2	1	1	6	0.7
I may be aware but not uncomfortable	1	0	1	8	0.9
I will have partial or total amnesia and have reduced anxiety and pain	1	1	1	7	0.8
Common risks					
Anxiety and/or discomfort	0	1	4	5	0.9
An unconscious state	0	1	3	6	0.9
Difficulty breathing and low blood oxygen levels	1	1	3	5	0.8
Bruising	4	2	1	3	0.4
Specific issues to you and your procedure	0	0	3	7	1.0
Declaration of anaesthetist obtaining consent					
I have completed a thorough preoperative anaesthetic evaluation of my patient	2	2	2	4	0.6
I have informed the patient of the anaesthetic techniques and alternatives for the proposed procedure noted above, including benefits and possible complications	0	1	2	7	0,9
I have provided the patient with information specific to the anaesthetic techniques indicated above, including patient and procedure specific information	0	1	3	6	0.9
I have given the patient and family the opportunity to ask questions and to receive answers regarding the anaesthetic plan	0	1	1	8	0.9
Questions: there will be a few lines provided for the anaesthetist to write down questions asked by the patient	2	2	2	4	0.6
Anaesthetist name	1	0	0	9	0.9
Anaesthetist signature	1	0	1	8	0.9
Date	1	0	0	9	0.9
Declaration of patient					

I understand that anaesthesia services are necessary for the surgery	0	0	0	10	1.0
The anaesthetist has explained the anaesthetic techniques that may be used for the proposed procedures, including the risks that are specific to me, have been explained	0	0	0	10	1.0
I understand that the anaesthetist's role is to monitor my vital signs closely and that they may change during the surgery	1	2	1	6	0.7
The anaesthetist will take any actions necessary, at their discretion, and will act in my best interest	0	0	1	9	1.0
I understand that for a period of 24hrs after leaving the recovery room, I may not drive a vehicle or operate heavy equipment, sign legal documents or make binding decisions as I will be medicolegally incapacitated	0	0	0	9	0.9
I have had the opportunity to discuss and clarify any concerns about the anaesthetic with my anaesthetist	0	0	1	8	0.9
Patient's full name	0	0	0	10	1.0
Patient's signature	0	0	1	9	1.0
Patient/Guardian signature	0	0	1	9	1.0
Date	0	0	0	10	1.0

Thirty items were removed from the revised anaesthetic consent form. These items scored a rating of either 1 or 2. The items removed are shown in Table 2.

Table 2: List of items that were not rated as content valid

Anaesthetist
Qualification
Rank (Community service officer, Medical officer, Registrar, Consultant)
Additional lines for monitoring
Urine catheter: A pipe is placed in your urethra once you are unconscious. This will allow the anaesthetist to monitor how much urine you make during the surgery.
Nasogastric tube: A pipe is placed through your nose to your stomach. This will allow the anaesthetist to drain any excess air and stomach contents.
Fibreoptic intubation: This will be done awake or asleep. It will depend on your anaesthetist's judgment. A scope with a camera will be placed in your nostril this will help guide placement of a tube into your windpipe.
Transoesophageal echo: this is a special ultrasound placed in your oesophagus once you are asleep. It will be used to monitor your heart during the surgery
General anaesthesia

I will not be aware of the events and will not feel any pain during the operation.

Common risks
Bruising at the site of injections or intravenous lines
Headache
Blurred vision and dizziness
Less common risks
Temporary muscle pain
Mild allergic reactions to drugs or blood products (itching or rash)
Uncommon risks
Skin injury due to equipment used during surgery
Nerve injury due to positioning required for surgery
Rare risks (More likely or more severe if you smoke, are overweight or have co-morbid conditions such as diabetes and heart disease)
Malignant hyperthermia: Inherited muscle sensitivity to certain anaesthetic drugs. An uncontrollably high temperature with muscle rigidity.
Heart attack
Stroke
Pulmonary embolism – a clot in your lung (1:1000)
Obstruction in the breathing passages that cannot be readily controlled.
Hypoxia – a lack of oxygen that may result in brain damage or other organ failure
Death due to any cause – 1:100 000|
Spinal or epidural anaesthesia: Uncommon risks
Infection at the injection site
Temporary backache
Bruising
Nerve blocks: Uncommon risks
Injury to blood vessels
Monitored anaesthesia care
You will be rendered into a sleepy state either by a drug being injected into your bloodstream or breathed into your lungs.
Common risks
Bruising
Declaration of anaesthetist obtaining consent
I have completed a thorough preoperative anaesthetic evaluation of my patient
Questions: there will be a few lines provided for the anaesthetist to write down questions asked by the patient
Declaration of the patient
I understand that the anaesthetist's role is to monitor my vital signs closely and that they may change during the surgery

The CVI was used to assess the content validity of the revised anaesthetic consent form. It is suggested that for a new instrument to be content valid, it has to have a minimum content validity index score of 0.8. This index is the percentage of items the experts rated as 3 or 4, therefore regarding them as being relevant. In this study, 65 out of 95 (68%) items were judged to be relevant by the experts. The CVI of this entire instrument is, therefore, 0.68.

Discussion

Informed consent is influenced by both a legal and moral component (14). The use and usefulness of a separate consent form for anaesthesia have been a subject of ongoing debate (15). The Association of Anaesthetists of Great Britain and Ireland (AAGBI) (16)state that a separate written consent form is not required if it is to facilitate another procedure and that the manner in which consent is obtained is more important than a signature on a consent form. Arguments that are in favour of a separate anaesthetic consent form state that anaesthesia is unique in its nature, purpose and complications, much like any surgical speciality (15,17). Rampersad et al (15) concluded that having a separate anaesthetic consent improved patients' understanding of the whole anaesthetic process. The authors showed that common side effects and complications were better understood by the patients. White (18) suggests that a separate anaesthetic consent form could prompt the anaesthetist to have a discussion with the patient. The South African law (9,10), does not require a separate consent form for anaesthesia, however, it is suggested by SASA (12).

The current consent forms that are available on the SASA website are the green anaesthetic form, the epidural consent form and consent form for upper limb blocks. The epidural consent and upper limb block consent forms are detailed and provide information regarding the procedure as well as the risks and complications related to each. However, not all aspects of the green anaesthetic form comply with the legal requirements set by the HPCSA (11). The consent form developed in this study aims to comply closely with the HPCSA legal requirements.

The HPCSA guidelines (11) state that patients have the right to be told the name of the doctor who will be treating them. SASA (12) states that patients have the right to ask about the anaesthetist's qualifications and experience. The SASA green anaesthetic form complies with what is required by the HPCSA in this

regard. The experts, however, only rated “Name” of anaesthetist as content valid, whereas “Qualification” and “Rank” of anaesthetist received a CVI of 0.7 and 0.5 respectively.

It is required by law to inform patients of their health status. The SASA green anaesthetic form addresses this under Section D, where the patient is provided with a list of conditions and is expected to tick those that he or she suffers from and it allows space for more detail to be provided. The patients’ health status is addressed under the section “Specific issues to you and your procedure” of the consent form developed in this study. This section will allow the anaesthetist to fulfil their legal obligation of detailing what was discussed with the patient. This will include risks that are specifically related to patients’ medical conditions as well as to the particular procedure and/or anaesthetic planned. This section received a CVI of 1.0.

The experts agreed that patients should be informed of the range of procedure options available and how they will be performed. Under Section 6 of the National Health Act 61 of 2003 (10) it states that an explanation of consequences, benefits and risks that are generally associated with each treatment option is a legal requirement. SASA (12) requires that all information, as well as common and relevant risks associated with the planned anaesthetic, is explained to the patient. Despite SASA’s requirement, the green anaesthetic form does not have evidence of this.

There were 19 items under ‘Risks’ associated with the different modalities of anaesthesia that the national experts felt were not relevant and should not be included. The healthcare practitioner, however, is required to give patients information that could influence a reasonable person in his position when making a decision (8). In 1993, the concept of material risk emerged in the Australian High Court and was defined as “a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is, or should reasonably be aware that the particular patient if warned of the risk, would be likely to attach significance to it" (6). In the Castell versus De Greef (8) case, the judge supports the criteria of material risk as described in the Rogers versus Whitaker (19) case in Australia and specifically states “the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it”. The South African case laws

(8) went a step further than the legislation (10) to say that patients not only need to be given knowledge but that they need to have understood the knowledge given. Furthermore, the case of Lourens versus Oldwange (20) shed light on how small a risk a complication must have for a doctor to not be found negligent in not making the patient aware of it.

The process of informed consent may not always result in the patient consenting to the procedure, as the patient has an equal right to informed refusal of treatment. Both the SASA green anaesthetic form (21)and the consent form developed in this study do not take into account written consent for the refusal or withdrawal of treatment, nor do they inform patients of the implications, risks or obligations of such a refusal or withdrawal.

The consent form developed in this study did not address the costs associated with each anaesthetic option. It aimed to improve the consent process in public healthcare where the majority of the services do not have any cost implications for the patient. Therefore, an amendment would have to be made to the consent form for the private sector. One of the requirements of the legislation is that the information provided to patients should be given in a language and at a level that the patient understands (10). The SASA green anaesthetic form and the consent form developed are only in English. Once the validation process of this consent form is complete it should be translated into all the official South African languages.

A limitation of the study is that it involved only one of the stakeholders, the anaesthetists. The second phase of the study will include patients and the legal team as stakeholders. CVI of 0.68 shows that even among anaesthesiologists there is not complete consensus as to what should be included on an anaesthetic consent form. Including other stakeholders could give more clarity.

Conclusion

The principle of informed consent plays an important role in anaesthesia as it is an ethical and legal requirement to obtain before any procedure is done to a patient. To ensure that legal requirements are met and that patients' rights to autonomy are upheld, written anaesthetic consent should be regarded as standard practice.

CVI of 0.68 indicates that controversy exists as to what should be included on a consent form and that more work needs to be done to reach consensus.

Conflict of interest

The authors declare that we have no financial or personal relationships which may have inappropriately influenced us in writing this paper.

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References

1. Murray PM. The history of informed consent. Iowa Orthop J. 1990;10:104–9.

2. Wolverton S, Kapp M. Informed consent and risk management. In: Wolverton S,

Wu J (eds) Comprehensive dermatologic drug therapy. 3rd Edition. Edinburgh, UK: Saunders Elsevier; 2013. p. 766–70.

3. Faden RR, Beauchamp TL. A history and theory of informed consent. 1st Edition. New York, NY: Oxford University Press; 1986.

4. Salgo v. Leland Stanford Etc. Bd. Trustees, 317 P.2d 170, 154 Cal. App. 2d 560 [Internet]. CourtListener. 1957 [cited 2020 Jun 22]. Available from: https://www.courtlistener.com/opinion/2619445/salgo-v-leland-stanford-etc-bdtrustees/

5. Rees AM. Communication in the physician-patient relationship. Bull Med Libr Assoc. 1993 Jan;81(1):1–10.

6. Braun AR, Skene L, Merry AF. Informed consent for anaesthesia in Australia and New Zealand. Anaesth Intensive Care. 2010 Sep;38(5):809–22. doi:10.1177/0310057X1003800504

7. South African Supreme Court. Richeter versus Estate Hammann. S Afr Law Rep. 1976;(3):226–35.

8. South African Supreme Court. Castell versus De Greef. S Afr Law Rep. 1994;1994(4):408–41.

9. Republic of South Africa. Constitution of the Republic of South Africa Nr 108 of 1996.

10. Republic of South Africa. The National Health Act 61 of 2003.

11. Health Professions Council of South Africa. Guidelines for good practice in the health care professions. Seeking patients' informed consent: The ethical considerations. Booklet 4 [Internet]. Pretoria. 2016 [cited 2019 May 30]. Available from: https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf

12. South African Society of Anaesthesiologists. Practice Guidelines Revision 2018 [Internet]. 2018 [cited 2019 May 30]. Available from: https://sasaapi.sasaweb.com/Document/SAJAA(V24N1)2061SASAPracticeGuidelines_V12_636803016948256880.pdf

13. Lynn, M. Determination and quantification of content validity. Nurs Res. 1986;35(6):382–5. doi:10.1097/00006199-198611000-00017.

14. Young R. Informed consent and patient autonomy. In: Kuhse, H, Singer, P (eds) A companion to bioethics. Second Edition. Malden, MA: Blackwell Publishing Ltd; 2009. p. 530–40.

15. Rampersad K, Chen D, Hariharan S. Efficacy of a separate informed consent for anesthesia services: A prospective study from the Caribbean. J Anaesthesiol Clin Pharmacol. 2016;32(1):18–24. doi:10.4103/0970-9185.173364

16. Yentis SM, Hartle AJ, Barker IR, Barker P, Bogod DG, Clutton-Brock TH, et al. AAGBI: Consent for anaesthesia 2017: Association of Anaesthetists of Great Britain and Ireland. Anaesthesia. 2017 Jan;72(1):93–105. doi:10.1111/anae.13762

17. White SM, Baldwin TJ. Consent for anaesthesia. Anaesthesia. 2003;58(8):760–74. doi:10.1046/j.1365-2044.2003.03202.x

18. White SM. Consent for anaesthesia. J Med Ethics. 2004 Jun 1;30(3):286–90. doi:10.1136/jme.2002.001610

19. Australian High Court. Rogers versus Whitaker. Aust Law J. 1993 Jan;67(1):47–55.

20. South African Supreme Court of Appeal. Louwrens versus Oldwage 2006 (2) SA 161 (SCA).

21. South African Society of Anaesthesiologists. Green Anaesthettic Form [Internet]. [cited 2020 Aug 9]. Available from: https://sasaapi.sasaweb.com//Newsletters/SASAGreenAnaestheticForm_2020.pdf_637193337148984265.pdf

Section 4: Proposal

Development and validation of an anaesthetic consent form

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4.1 Introduction and problem statement

In ancient Greece, it was not common practice to explain medical risks to patients as it was believed that it would decrease the trust they had in their physician's capability (1). Informed consent was first introduced to medical practice in the eighteenth century under the English common law, whereby patients gave or withheld permission to medical care (2). The Nuremberg Code document drafted, in 1947, recognised the importance of informed consent in research and it was then extended to the medical practice as a fundamental principle and paved the movement away from the paternalistic approach of practice (3).

An example of how informed consent evolved over the years is the case of Mr Salgo, whose healthcare practitioner, in 1957, failed to disclose the possible complications during a translumbar aortography, which resulted in Mr Salgo suffering from permanent paralysis (4). This Californian case changed the way in which medicine was practised as after this, it became a requirement for physicians to explain the risks and benefits of the planned procedure including the alternatives (5)

Informed consent was introduced into South African Law in 1994 following the case of Castell versus De Greef (6). This case illustrates a medical practitioner found guilty for not disclosing complications to a patient undergoing an elective prophylactic double mastectomy and simultaneous breast reconstruction and flap procedure.

Informed consent is influenced by both a legal and moral component (7). Informed consent is guided by the four ethical principles, autonomy, beneficence, nonmaleficence and justice. The Association of Anaesthetists of Great Britain and Ireland (AAGBI) (8) defined consent as a "state of mind", whereby the patient has the right to decide whether to accept or refuse consent to examination, investigation or treatment. The main aim of informed consent is to respect and protect the patient's individual autonomy, but as White and Baldwin stated this may not always be possible due to variables such as cultural differences, socioeconomic status and mental capacity (9).

The current practice in South Africa regarding having a consent form for surgery and a consent form for anaesthesia differs as it is not standardised in the public

and private sectors. There are some institutions that have one consent form and others that will have a separate consent form for surgery and for anaesthesia.

The topic regarding having two consent forms is still controversial among the anaesthetic community. It is argued that anaesthesia is a unique speciality and should be given merit regarding its purpose and complications, much like any surgical speciality (10). It is, however, argued that a separate signed anaesthetic consent form is not necessary if it is to facilitate another procedure, for example meaning that a patient who has signed consent for surgery has implied consent to having an anaesthetic (8). The AAGBI (8) suggests that the importance lies more in the communication process in which the consent is obtained rather than having a signature on a consent form, which only proves that a conversation has taken place and not what has been discussed. It is argued by Rampersad et al (10) and Singh (11) that a separate anaesthetic consent form improved patients' understanding of the whole anaesthetic process as well as the common side effects and complications.

Informed consent in South Africa is mainly informed by The Constitution of the Republic of South Africa (12) and the National Health Act (13). The Health Professions Council of South Africa (HPCSA) (14) has published a guideline for obtaining informed consent based on the statutory requirements. The recommendations regarding informed consent made by the HPCSA cannot be fulfilled by a one-line item on the surgery consent form.

The South African Society of Anaesthesiologists (SASA) is a member association that is dedicated to the "furtherance of the discipline of anaesthesia at both an academic and clinical level" (15). The Society's Practice Guidelines (15) suggest that it is a requirement to obtain a separate informed consent for patients undergoing anaesthesia as the standard of care.

Informed consent is an integral part of daily anaesthetic practice. It is an important clinical entity as well as a medico-legal obligation to inform patients of the risks of anaesthesia. There is no consent form for anaesthesia at the hospitals affiliated to the Department of Anaesthesiology at the University of the Witwatersrand (Wits). The practice is verbal and consent is implied with a one-line item on the surgical consent form. This practice does not ensure patients' understanding of the risks, benefits, complications as well as alternative anaesthetic techniques available but

more importantly does not comply with medico-legal requirements for informed consent.

4.2 Aim and objectives

4.2.1 Aim

The aim of this study is to develop and validate an anaesthetic consent form for surgery at the Wits affiliated hospitals using the two-stage Lynn's Model (16).

4.2.2 Objectives

The objectives of this study are to**:**

- develop a provisional anaesthetic consent form for surgery from the literature using Lynn's Development Stage (domain identification and item generation)
- develop a revised anaesthetic consent form using Lynn's Development Stage (item formation)
- determine content validity of the anaesthetic consent form using Lynn's Judgement/Quantification Stage (16).

4.3 Research assumptions

The following definitions will be used in this study.

Lynn's Model: a model described by Lynn (16) that involves a two-stage process in developing an instrument and achieving content validity of the instrument.

Anaesthesiologist: is a medical doctor who has undergone postgraduate training and examination in anaesthesia and is registered as a specialist in anaesthesiology with the HPCSA.

Expert: an anaesthesiologist or other professional who is knowledgeable in the medico-legal field and has a good standing in the healthcare community.

Provisional anaesthetic consent form: this form will be developed by the researcher after an extensive review of the literature of what should be included on an anaesthetic consent form.

Revised anaesthetic consent form: this will be the amended provisional anaesthetic consent form following the group discussion during the Development Stage.

Anaesthetic consent form: this will be the final anaesthetic consent form that was validated by the national experts during the Judgement/Quantification Stage.

Wits Affiliated hospitals: this study will include the Charlotte Maxeke Johannesburg Academic Hospital, Chris Hani Baragwanath Academic Hospital, Helen Joseph Hospital and Rahima Moosa Mother and Child Hospital.

4.4 Ethical considerations

Ethical approval will be obtained from the Human Research Ethics Committee (Medical) and the Graduate Studies Committee of Wits. Consent to conduct the study was obtained from the Head of Department of Anaesthesiology (Appendix 1).

Experts will be invited to participate in this study. An information letter will be mailed to the participants in the Developmental Stage (Appendix 2) and participants in the Judgement/Quantification Stage (Appendix 3). The participants will be asked to sign a consent form agreeing to participate (Appendix 4).

Anonymity cannot be ensured in either of the stages as a purposive sampling method will be used and the participants will be known. However, the data captured will contain no identifying information about any participant. Only the researcher and supervisors will have access to the raw data collected. Participants of the discussion group will be requested not to divulge any information during discussions.

The data will be stored securely in a password protected database for six years after completion of the study.

The study will be conducted according to the principles of the Declaration of Helsinki (17) and the South African Guidelines for Good Clinical Practice (18).

4.5 Research methodology

4.5.1 Research design

A prospective, exploratory and instrumental design will be used for the study.

A prospective study is one where a population is identified and variables are measured at the time the study takes place (19). This study is prospective as data will be collected as the study progresses.

An exploratory study aims to explore and describe phenomena. This approach aims to increase the knowledge of anaesthetic consent for surgery (20).

This study is instrumental as specific rules, as proposed by Lynn's Model (16), will be applied to develop an anaesthetic consent.

4.5.2 Study method

Lynn's Model (16) will be used as the study method. It is a two-stage process that consists of a Development Stage and a Judgement/Quantification Stage. This will be used to determine the content validity of an anaesthetic consent form that will be developed.

4.5.3 Study population

The study population will consist of local and national experts

4.5.4 Study sample and sample method

According to Lynn's Model (16), the number of experts chosen in the two stages is arbitrary, as it depends on how many experts are accessible, available and willing. The author suggests that a minimum of five experts would provide a sufficient level of control for chance agreement and that the maximum number of participants has not been established but does not usually exceed 10 (16).

A purposive sampling method will be used in this study. It is a type of nonprobability sampling based on the judgement of the researcher (20). Burns and Grove (20) sometimes refer to it as sampling that is judgemental or selective as the researcher "selects certain participants, elements, events, or incidents to

include in the study" which are advantageous for the study. There is, however, a potential for sampling bias (19).

Experts from both the public and private sector will be invited, ensuring a minimum of five participants for the Development Stage and a minimum of 10 participants for the Judgement/Quantification Stage. The experts who participated in the Development Stage will be excluded from the Judgement/Quantification stage.

4.6 Data collection

Developmental Stage

The Development Stage of Lynn's Model (16) consists of three steps: domain identification, item generation and instrument formation. Domain identification will be done by an extensive review of the literature by the researcher on what should be included in an anaesthetic consent form. This step will be followed by the researcher generating a provisional anaesthetic consent form (item generation). Lastly, a group discussion will be held to debate and refine the provisional anaesthetic consent form in order to develop the revised anaesthetic consent form (instrument formation).

The local experts identified will be sent an information letter (Appendix 2), inviting them to participate in the study. The provisional anaesthetic consent form with preparation instructions (Appendix 5) will be mailed to the experts accepting the invitation.

The peer group discussion will be scheduled after a combined departmental meeting and will be conducted in the Anaesthesiology Research Office. On arrival, light refreshments will be available. Experts will be asked to sign consent forms (Appendix 4). The experts will be expected to refine the provisional anaesthetic consent form to improve the content validity of the instrument by making recommendations, additions or deletions. Each item will be debated until 100% consensus is reached.

The peer group discussion will be conducted by the researcher. The experts will be expected to review and grade the items on the provisional anaesthetic consent form according to the following scale by determining whether each item was:

- 1 = Not important information
- 2 = Useful information
- 3 = Important information
- 4 = Essential information.

All the items on the provisional anaesthetic consent form need to have full consensus from all the experts. Changes will be made to the provisional anaesthetic consent form instrument according to the recommendations made by the peer group discussion in preparation for the Judgement/Quantification Stage. The revised anaesthetic consent form will be given to two participants to verify the changes made.

Judgement/Quantification Stage

The Judgement/Quantification stage of Lynn's Model has two steps. The first is the assertion by a specific number of experts that the items of the list are content valid. The second step is the assertion that the entire list is content valid (16).

Lynn (16) states that the quantification of content validity can be achieved using the content validity index (CVI). The CVI is derived from rating items using a Likert rating scale. A four-point rating scale is preferable because it does not include the ambivalent middle rating common in odd number rating scales. The same four-point Likert scale used in the Development Stage will be used in this stage.

An e-mail will be sent to identified local and national experts to invite them to take part in this stage (Appendix 3). Those who agree to participate in the study will be e-mailed the revised anaesthetic consent form and instructions (Appendix 6).The experts are expected to rate each item using the four-point Likert scale provided and return the rated anaesthetic consent form by e-mail.

The researcher will enter the data collected during this stage onto a Microsoft Office Excel® spreadsheet. Firstly, the CVI for each item will be determined by the proportion of experts who rated it as content valid with a rating of three or four on the rating scale. Secondly, the CVI of all the items on the consent form is determined. The CVI validity index for the entire consent form is the proportion of items judged as content valid.

4.7 Data analysis

Lynn (16) makes use of cumulative binomial distribution to determine the proportion of experts needed to rate an item as valid. Cumulative binomial distribution is published as standard norms (16).

4.8 Significance of the study

The study will be significant in that it will provide an anaesthetic consent form that will be developed and validated by experts in the anaesthesia or medico-legal field for the Wits affiliated hospital context. This will ensure that patients have a better understanding of the risks, benefits, complications and alternative treatments regarding their anaesthetic. A separate anaesthetic consent form will enable anaesthetists to fulfil their medico-legal and constitutional requirement to any patient under their care.

4.9 Validity and reliability of the study

Validity refers to the degree to which a measurement represents a true value and the reliability of a study represents the consistency of the measure achieved (21). The validity and reliability of this study will be ensured by: using an appropriate study design the two-stage validated process described by Lynn (16) will be used to determine and quantify that each item, as well as the anaesthetic consent form in its entirety, is content valid participants will be carefully selected for their expertise or interest in the medico-legal field all data entered into the Microsoft Office Excel® spreadsheet will be checked for accuracy.

The validity and reliability of the anaesthetic consent form will be ensured by:

- an extensive review of the literature to generate items for the development of the provisional anaesthetic consent form
- using a minimum of five local experts during the Development Stage
- using a four-point Likert scale and debating items until 100% consensus is reached
- using a minimum of 10 national experts to validate each item and the anaesthetic consent form as a whole using the four-point Likert scale.

4.10 Potential limitations

A poor response from experts to the invitation to participate in the Development and Judgement/Quantification stages of the anaesthetic consent form may pose a potential limitation.

4.11 Project outline

4.11.1 Time frame

Activity	May 2019	Jun 2019	Jul - Dec 2019	Jan 2020	Feb 2020	Mar 2020	Apr 2020	May 2020	Jun 2020	Jul 2020
Proposal preparation										
Literature review										
Proposal submission										
Ethics approval										
Postgraduate approval										
Data collection										
Data analysis										
Draft article										
Submission										

4.11.2 Budget

Item	Price per page	Number of pages	Copies	Total
Proposal	1	23	6	R 138
Consent form	1	1	10	R10
Postgraduate form	1	2	6	R 12
Complete report	1	100	4	R 400
Binding	R200		3	R600
Grand total				**R 1160**

The Wits Department of Anaesthesiology will incur the costs of paper and printing for the Postgraduate application, the information letters and consent forms.

4.12 References

1. Murray PM. The history of informed consent. Iowa Orthop J. 1990;10:104–9.

2. Wolverton S, Kapp M. Informed consent and risk management. In: Wolverton S, Wu J (eds) Comprehensive dermatologic drug therapy. 3rd Edition. Edinburgh, UK: Saunders Elsevier; 2013. p. 766–70.

3. Faden RR, Beauchamp TL. A history and theory of informed consent. 1st Edition. New York, NY: Oxford University Press; 1986.

4. de Roubaix JA. Seeking patients' consent in anaesthesiology: consent in clinical practice. South afr J Anaesth Analg. 2005;11(4):125–7. doi:10.1080/22201173.2005.10872412

5. Dyer R. Informed consent for epidural analgesia in labour. South afr J Anaesth Analg. 2007;13(1):27–34. doi:10.1080/22201173.2007.10872462

6. South African Supreme Court. Castell versus De Greef. S Afr Law Rep. 1994;1994(4):408–41.

7. Nanda A, Nasser M. Informed consent and medico legal aspects of neurosurgery. In: Complications in Neurosurgery. 1st Edition. Edinburgh, UK: Elsevier; 2019. p. 6–9.

8. Yentis SM, Hartle AJ, Barker IR, Barker P, Bogod DG, Clutton-Brock TH, et al. AAGBI: Consent for anaesthesia 2017: Association of Anaesthetists of Great Britain and Ireland. Anaesthesia. 2017 Jan;72(1):93–105. doi:10.1111/anae.13762

9. White SM, Baldwin TJ. Consent for anaesthesia. Anaesthesia. 2003;58(8):760–74. doi:10.1046/j.1365-2044.2003.03202.x

10. Rampersad K, Chen D, Hariharan S. Efficacy of a separate informed consent for anesthesia services: A prospective study from the Caribbean. J Anaesthesiol Clin Pharmacol. 2016;32(1):18–24. doi:10.4103/0970-9185.173364

11. Singh TSS. Is it time to separate consent for anesthesia from consent for surgery? J Anaesthesiol Clin Pharmacol. 2017;33(1):112–3. doi:10.4103/09709185.202206

12. Republic of South Africa. Constitution of the Republic of South Africa Nr 108 of 1996.

13. Republic of South Africa. The National Health Act 61 of 2003.

14. Health Professions Council of South Africa. Guidelines for good practice in the health care professions. Seeking patients' informed consent: The ethical considerations. Booklet 4 [Internet]. Pretoria. 2016 [cited 2019 May 30]. Available from: https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf

15. South African Society of Anaesthesiologists. Practice Guidelines Revision 2018 [Internet]. 2018 [cited 2019 May 30]. Available from: https://sasaapi.sasaweb.com/Document/SAJAA(V24N1)2061SASAPracticeGuidelines_V12_636803016948256880.pdf

16. Lynn, M. Determination and quantification of content validity. Nurs Res. 1986;35(6):382–5. doi:10.1097/00006199-198611000-00017.

17. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013;310(20):2191–4. doi:10.1001/jama.2013.281053

18. Department of Health. Guidelines for good practice in the conduct of clinical trials with human participants in South Africa [Internet]. 2006 [cited 2019 May 24]. Available from: http://www.kznhealth.gov.za/reaearch/guidleline2.pdf

19. Brink, H. Fundamentals of research methodology for health care professionals. 2nd Edition. Cape Town, SA: Juta; 2006.

20. Burns N, Grove S. The practice of nursing research. Sixth Edition. St Louis, MO: Saunders Elsevier; 2009.

21. Botma Y, Greef M. Research in health sciences. Cape Town, SA: Heinemann; 2010.

4.13 Appendices

Appendix 1: Letter from Head of Department of Anaesthesiology

Dr Karyll Mae San Pedro

Department of Anaesthesiology

University of Witwatersrand

28 May 2019

RE: DR KARYLL MAE SAN PEDRO STUDENT NUMBER 2051670

I herewith grant permission to Dr Karyll Mae San Pedro to conduct the study titled **"Development and validation of an anaesthetic consent form"** at the University of the Witwatersrand Department of Anaesthesiology.

Yours sincerely,

Dr Palesa Motshabi

Head of Department of Anaesthesiology

University of the Witwatersrand

Appendix 2: Information letter for the experts in the Developmental Stage

Dr Karyll Mae San Pedro

Anaesthesiology Registrar

University of Witwatersrand

Dear Colleague

Hello, my name is Karyll Mae San Pedro. I am a registrar in the Department of Anaesthesiology at the University of the Witwatersrand. I am conducting a research study titled: **Development and validation of an anaesthetic consent form** as part of my M Med degree.

The motivation behind this study is that there is currently no anaesthetic consent form for surgery at the Wits affiliated hospitals. This will ensure that patients have a better understanding of the risks, benefits, complications and alternative treatments regarding their anaesthetic. The anaesthetic consent form will also benefit anaesthetists from a medico-legal point of view.

The study will be conducted using Lynn's Model[1] to develop and validate the instrument. There are two-stages (Development and Judgement/Quantification stage) that will be used to determine the content validity of the anaesthetic consent form.

I hereby invite you as an expert in the anaesthesia or medico-legal field to be part of the peer group discussion for the Development Stage of this anaesthetic consent form. Participation in this process is entirely voluntary. If you accept this invitation, I will send you more information pertaining to the study.

The email will include the provisional draft anaesthetic consent form that I have developed from the literature. You will be part of a peer group discussion with other experts in your field. You will be given the task to refine and improve the

[1] Lynn, M. Determination and Quantification of Content Validity Nursing Research. Nurs Res. 1986;35(6):382–5. doi:10.1097/00006199-198611000-00017.

content validity of the anaesthetic consent form by rating each item as being content valid using a four-point Likert scale.

The revised anaesthetic consent form at the end of the peer group discussion will be prepared for the Judgement/Quantification Stage.

Participants will be requested to maintain confidentiality of what is discussed, but I as the researcher, cannot guarantee that this will be adhered to.

The study has been approved by the Human Research Ethics Committee (HREC) and the Graduate Studies Committee, University of the Witwatersrand.

Should you require any further information, you can contact:

- Karyll Mae San Pedro cell: 072 432 8023 e-mail: karyllmae@gmail.com
- The chairman of the HREC (Medical) Chairperson -Prof Clement Penny 0117172301.

Thank you for taking the time to read this invitation letter.

Yours sincerely,

Karyll Mae San Pedro

Appendix 3: Information letter for the experts in the Judgement/Quantification Stage

Dr Karyll Mae San Pedro

Anaesthesiology Registrar

University of Witwatersrand

Dear Colleague

Hello, my name is Karyll Mae San Pedro. I am a registrar in the Department of Anaesthesiology at the University of the Witwatersrand. I am conducting a research study titled: **Development and validation of an anaesthetic consent form** as part of my M Med degree.

The motivation behind this study is that there is currently no anaesthetic consent form for surgery at the Wits affiliated hospitals. This will ensure that patients have a better understanding of the risks, benefits, complications and alternative treatments regarding their anaesthetic. A separate anaesthetic consent form will also benefit anaesthetists from a medico-legal point of view.

The study will be conducted using Lynn's Model[2] to develop and validate the instrument. There are two-stages (Development and Judgement/Quantification Stage) that will be used to determine the content validity of the anaesthetic consent form. The Development Stage was done following a review of the literature and a peer group discussion that resulted in the development of a revised anaesthetic consent form.

I hereby invite you as an expert in the anaesthesia or medico-legal field to participate in my study. If you accept this invitation, I will send you the revised anaesthetic consent form. You will be tasked to rate each item on this anaesthetic consent form as being content valid and then the anaesthetic consent form as a whole on a four-point Likert scale.

---

[2] Lynn, M. Determination and Quantification of Content Validity Nursing Research. Nurs Res. 1986;35(6):382–5. doi:10.1097/00006199-198611000-00017.

Participation in this process is entirely voluntary. I, the researcher, will be the only person knowing your identity and I will capture the data in a way that does not identify information of any participant, thereby ensuring confidentiality.

The study has been approved by the Human Research Ethics Committee (HREC) and the Graduate Studies Committee, University of the Witwatersrand.

Should you require any further information, you can contact:

- Karyll Mae San Pedro cell: 072 432 8023 e-mail: karyllmae@gmail.com • The chairman of the HREC (Medical) Chairperson -Prof Clement Penny 0117172301.

Thank you for taking time to read this information letter.

Yours sincerely,

Karyll Mae San Pedro

Appendix 4: Consent form for the experts

CONSENT FORM

Development and validation of an anaesthetic consent form

I,_____ (full name), fully understand the contents of the information letter detailing the purpose of the study and how the study will be performed.

I hereby consent to participate in this study.

_____	_____
Participant Signature	Date
_____	_____
Researcher Signature	Date

Appendix 5: Instructions letter for the experts in the Developmental Stage

Dr Karyll Mae San Pedro

Anaesthesiology Registrar

University of Witwatersrand

Dear Colleague,

Thank you for agreeing to participate in my study titled **"Development and validation of an anaesthetic consent form"** as part of my M med degree.

The peer group discussion will be arranged after the Wednesday Departmental meeting at the Anaesthesiology research office at Medical School. Light refreshments will be available. You will be asked to sign a consent form to participate in the study.

I have attached the provisional anaesthetic consent form that I have developed from the literature. You will be asked to rate each item on the provisional anaesthetic consent form as being content valid on a four-point Likert scale:

- 1 = Not important information
- 2 = Useful information
- 3 = Important information
- 4 = Essential information

Each item on the provisional anaesthetic consent form will be debated and items that reach a 100% consensus will be included in the revised anaesthetic consent form. The revised anaesthetic consent form will be prepared for the Judgement/Quantification stage.

I appreciate that you will not benefit from participation in this study, however I hope that the development of this anaesthetic consent instrument will lead to improved documentation of the anaesthetic process as well as a patient who is more informed. These will be invaluable in enhancing patient understanding of the risks and benefits of anaesthesia and the alternative treatments available.

The study has been approved by the Human Research Ethics Committee (HREC) and the Graduate Studies Committee, University of the Witwatersrand.

Should you require any further information, you can contact:

- Karyll Mae San Pedro cell: 072 432 8023 e-mail: karyllmae@gmail.com
- The chairman of the HREC (Medical) Chairperson -Prof Clement Penny 0117172301.

Thank you for taking time to read this information letter.

Yours sincerely,

Karyll Mae San Pedro

Appendix 6: Instructions letter for the experts in the Judgemental/Quantification Stage

Dr Karyll Mae San Pedro

Anaesthesiology Registrar

University of Witwatersrand

Dear Colleague,

Thank you for agreeing to participate in my study titled **"Development and validation of an anaesthetic consent form"** as part of my M med degree.

I have attached the revised anaesthetic consent form that was developed from the literature and refined during a peer group discussion during the Development Stage.

You will be asked to rate each item on the revised anaesthetic consent form and the anaesthetic consent form as a whole as being content valid on a four-point Likert scale:

- 1 = Not important information
- 2 = Useful information
- 3 = Important information
- 4 = Essential information

You will be asked to return the rated revised anaesthetic consent form to me via email. I will enter the data collected during this stage onto a Microsoft Office Excel® spreadsheet. Firstly, the content validity index (CVI) for each item will be determined by the proportion of experts who rated it as content valid with a rating of three or four on the rating scale. Cumulative binomial distribution is published as standard norms that determine the proportion of experts needed to rate an item as valid. Secondly, the CVI of all the items on the consent form is determined. The CVI validity index for the entire consent form will be calculated as the proportion of items judged as content valid.

I appreciate that you will not benefit from participation in this study, however I hope that the development of this anaesthetic consent form will lead to improved

documentation of the anaesthetic process as well as a patient who is more informed. These will be invaluable in enhancing patient understanding of the risks and benefits of anaesthesia and the alternative treatments available.

The study has been approved by the Human Research Ethics Committee (HREC) and the Graduate Studies Committee, University of the Witwatersrand.

Should you require any further information, you can contact:

- Karyll Mae San Pedro cell: 072 432 8023 e-mail: karyllmae@gmail.com • The chairman of the HREC (Medical) Chairperson -Prof Clement Penny 0117172301.

Thank you for taking time to read this information letter.

Yours sincerely,

Karyll Mae San Pedro

Section 5: Annexures

5.1 SASA green anaesthetic form



ANAESTHESIA FORM NARKOSEVORM

LEES ASSEBLIEF AFDELINGS A, B, C, & D, VUL GEGEWENS IN, TEKEN ONDER EN OORHANDIG AAN DIE NARKOTISEUR.
L.W. AFDELING C MOET INGEVUL WORD DEUR DIE REKENINGPLIGTIGE

PLEASE READ AND COMPLETE SECTIONS A, B, C, & D, SIGN BELOW AND HAND TO THE ANAESTHESIOLOGIST.
N.B.SECTION C. MUST BE COMPLETED BY THE PERSON RESPONSIBLE FOR THE ACCOUNT.

A OOREENKOMS TUSSEN DIE ANESTESIOLOOG EN PASIËNT
AGREEMENT BETWEEN THE ANAESTHESIOLOGIST AND PATIENT

PASIËNT:

A1. Ek begryp dat' n insidentvrye narkose nie gewaarborg kan word nie.
A2. Ek begryp dat teatertoerusting en personeel deur die hospitaal verskaf word. Narkosetoerusting word daagliks getoets.
A3. Ek onderneem om nie alkohol te gebruik, 'n motorvoertuig te bestuur, sosiale media te gebruik, om die alleen-verantwoordelike te wees vir 'n baba of minderjarige kind, enige gevaarlike toerusting te hanteer, belangrike besluite te neem of dokumente te teken vir 'n tydperk van 24 uur nadat narkose toegedien is nie.
A4. Ek verleen toestemming dat my persoonlike inligting bekend gemaak mag word aan belanghebbende instansies, soos deur die wet bepaal, asook anonieme data van 'n kliniese en praktykbesturende aard wat tot die bevordering van die pasiënt se welstand mag bydra.
A5. Ek stem toe tot die verwerking van my persoonlike en gesondheidsinligting ten einde behoorlike behandeling aan my te verskaf. en/of vir administratiewe doeleindes deur die betrokke inrigting of professionele praktyk. Hierdie toestemming betrek ook die verantwoordelike partye wat optree as diensverskaffers aan die inrigting of professionele praktyk.
A6. In die geval van enige eis, klagte of grief, sal ek voordat ek enige regsaksie neem, gebruik maak van 'n gratis en konfidensiële premediasievergadering met 'n geakkrediteerde bemiddelaar aangewys deur South African Society of Anaesthesiologists (SASA).
A7. U narkose rekening is totaal onafhanklik van enige ander rekening wat deur die hospitaal of chirurg uitgereik word.
A8. Die koste (beraming) vir die narkose is met my bespreek.
A9. Die koste (beraming) soos uiteengesit in deel C is gebaseer op hoe lank die prosedure sal duur , en mag verander weens onvoorsiene omstandighede of onverwagte komplikasies.
A10. U is persoonlik verantwoordelik vir betaling van u rekening en nie u mediese fonds nie. U mediese fonds mag dalk nie die hele bedrag dek nie, afhangend van die mediese fonds en die plan opsie wat u gekies het.
A11. Sou u rekening oorhandig word vir invordering, sal rente van 2% per maand gehef word op alle agterstallige bedrae. Alle koste verbonde aan die invordering sal van u verhaal word teen prokureur en kliënte skaal.

Ek het bostaande gelees, begryp en aanvaar die voorwaardes soos uiteengesit.
Ek gee hiermee toestemming vir narkose soos verduidelik deur die anestesioloog en dit uit vrye wil doen. Hiermee gee ek toestemming vir narkose vir myself of my afhanklike.

GETEKEN: DATUM:

PATIENT:

A1. I understand that no one can guarantee an incident free anaesthetic.
A2. I understand that the theatre staff and equipment are supplied by the hospital. Anaesthetic equipment is checked on a daily basis.
A3. I agree not to drink alcohol, drive a car, utilise social media, be responsible as a sole care provider for infants/small children, operate any dangerous equipment, make important decisions or conclude agreements for 24 hours after recovering from anaesthesia.
A4. I agree to allow my personal data to be forwarded to the relevant organisations as required by law and to allow anonymous data of a clinical and practice management nature, to be collected to help to improve the patients healthcare experience.
A5. I agree to the processing of my health and personal information in order to provide me with proper treatment, care and/or for the administration of the institution or professional practice concerned. This consent would extend to responsible parties acting as service providers to the institution or professional practice concerned..
A6. In the event of any claim, complaint or grievance, I shall prior to taking any legal action, promptly initiate a free and confidential pre-mediation meeting with an accredited mediator appointed by South African Society of Anaesthesiologists (SASA).
A7. Your anaesthetic account is rendered completely independently from the accounts rendered by the hospital and the surgeon.
A8. The make up of the cost estimate for the anaesthetic service has been discussed with me.
A9. The cost estimate as set out in section C is time-based and may change as a result of unforeseen circumstances and unexpected complications.
A10. You are personally responsible for payment and not your medical scheme. Your medical scheme may not cover the full amount on your account, depending on the medical scheme and the plan option which you have chosen.
A11. Should your account be handed over for collection, interest will be charged at 2% per month on all outstanding amounts. All costs incurred to collect the arrears will be for your account on attorney and client scale.

I have read, understood and agree to the conditions mentioned above. / declare that I am of sound mind at the time of signing this agreement and that I am not under duress. I hereby give permission for anaesthesia on myself or my dependant.

SIGNED: DATE:

B PASIENT VAN : / PATIENT SURNAME : / VOLLE VOORNAME : / FIRST NAMES :
GEB.DATUM: / BIRTH DATE:

C PERSON RESPONSIBLE FOR ACCOUNT/MAIN MEMBER

MEDIESEFONDS : / MED.FUND : — OPSIE: / OPTION: — NOMMER : / NUMBER :
MAGTIGINGS No : / AUTHORIZATION No : — GAPINGDEKKING: / GAP COVER:
VAN : / SURNAME : — TITEL: / TITLE: — VOORLETTERS : / INITIALS :
POSADRES : / POSTAL ADDRESS : — POS KODE : / POSTAL CODE :
I.D. No : — SEL: / CEL:
TEL HUIS : / TEL HOME : — TEL WERK : / TEL WORK : — FAKS : / FAX :
WOONADRES : / RES. ADDRESS : — WERKGEWER : / EMPLOYER : — ADRES : / ADDRESS : — epos: / email:
FAMILIE/VRIEND: / FAMILY/FRIEND:
TEL: — KOSTE BERAMING: / COST ESTIMATE:

FOR MORE INFORMATION VISIT WWW.SASAWEB.COM

HOSPITAAL : — VR — DATUM:

CHIRURG :	0173	0145	0146
	0147	0151	
PROSEDURE :	KODE :		
NARKOSETYD : VAN : TOT : MIN		ICD 10	
	ASA	0039	MIN
	543	0011	MIN

0109	544
0026	1204
0032	1215
0034	1218
0038	1220
0042	1221
0043	1780
0044	2800
0019	2801
0018	2802
	2804
	5103

Anaesthesiologist

NO D

NO C

SASA SOUTH AFRICAN SOCIETY OF ANAESTHESIOLOGISTS

AMPTELIK OFFICIAL
PLAK HOSPITAAL PLAKKER HIER
PASTE HOSPITAL STICKER HERE

5.2 Epidural consent form

Hospital Sticker

EPIDURAL INFORMATION SHEET

SASA ACACIA
South African Society of Anaesthesiologists, Acacia Branch

Dear _____

An epidural injection can be given for one of the following possible reasons:

1. On the recommendation of an Orthopaedic Surgeon in the management of back complaints.
2. To manage post-operative or labour pain.

A computerized infusion pump that continuously supplies the local anaesthetic drug via an epidural catheter can also be used in the long term management of pain.

Epidural injections are safe and very effective in controlling pain. They are administered by an Anaesthesiologist who will also explain the technique to you. Please ask the Anaesthesiologist during the pre-operative visit to clarify any uncertainty you may have.

Anaesthesiologists exercise extreme care in administering epidural injections and infusions but, as with any medical procedure, complications can occur. The following complications are possible:

Common complications:

1. *Cardiovascular*: Your blood pressure may drop and you may feel lightheaded or dizzy. It is easy to treat this quickly and effectively.
2. *Nausea:* This is also easily treated.
3. *Shivering*
4. *Difficulty in passing urine*: Patients who have had an epidural are not permitted to leave the hospital before they are able to pass urine. Occasionally patients require a urinary catheter and have to be kept in hospital overnight. Patients with an epidural catheter for a constant infusion usually have their bladders catheterized until the epidural is stopped.

Rare complications:

1. *Failed block*: In rare cases the epidural injection may give unsatisfactory pain relief. The dosage of epidural drugs can then be adjusted or alternative methods of pain relief can be employed.

2. *Headache*: In some cases the outer covering of the spinal chord is inadvertently punctured and spinal fluid can leak through the defect caused. This can lead to headache which can respond to bed rest for a few days. If this is not effective a sample of your own blood can be withdrawn and injected aseptically into the space around the spinal chord to stop the leak.
3. *Backache*: You may suffer superficial pain of variable duration at the injection site.
4. *Prolonged or dense block*: We strive to give the minimum amount of local anaesthetic needed to provide satisfactory analgesia without interfering with limb movement. However, sometimes a block can have a prolonged or even a temporary paralyzing effect.

Very rare complications:

1. *Haematoma*(bleeding): Small blood vessels can be damaged during insertion of the epidural needle. In rare cases this can cause continuous internal bleeding. The resultant pressure on the spinal chord can lead to neurological damage and paralysis if not diagnosed and treated timeously. This treatment involves urgent surgical drainage of the haematoma. It is important that the attending Anaesthesiologist is made aware of any medication, including herbal products, that you are taking and that may interfere with blood clotting and thus may increase the risk of a spinal haematoma forming.
2. *Spinal block/high block*: If the unlikely event of the injected local anaesthetic entering the spinal fluid a very dense block that temporarily paralyzes the arms and the muscles of breathing can occur.
3. *Sepsis*: In spite of the strict aseptic techniques used, superficial skin infections or even an abcess close to the spinal chord are possible.
4. *Neurological damage*: This can occur during insertion of the epidural needle or catheter. Any undue discomfort during the procedure must be communicated to the anaesthesiologist immediately.
5. Rarely during removal of the epidural catheter it can be sheared off with a piece being retained in the epidural space. This may require surgical removal.
6. A few other extremely rare complications have also been documented.

Your Medical Aid Fund may pay only part of, or even none of, the fee for an epidural injection. Feel free to discuss this with the Anaesthesiologist.

I declare that I have read and understand the contents of this Information Sheet and that I have discussed any uncertain aspects with the attending Anaesthesiologist.

I hereby consent to having an epidural injection performed on me/ my dependant.

Signed at _____ Hospital on this the _____day of _____200__.

Signature_____ (patient/parent/guardian)

5.3 Upper limb block consent form

UPPER LIMB BLOCK INFORMATION SHEET

Dear _____

An upper limb block can be given for one of the following possible reasons:

1. As pain relief after your orthopaedic operation of your shoulder, arm or hand.
2. As anaesthesia for your orthopaedic operation of your arm or hand.

This block is administered through an injection at the side of the neck between the interscalene muscles or just above or below the clavicle. This is in general a very safe and effective method of pain relief for the shoulder, arm or hand. The block is administered by your anaesthesiologist who will explain the technique to you. Mostly this block is done with a nerve stimulator to identify the nerves involved when you are already asleep. The bundle nerves that supply the shoulder, arm and hand originates in both sides of the neck. We block these nerve bundles here in the neck by administering local anaesthetic. We sometimes block individual nerves lower down the arm. The block usually lasts for 8-10 hours, but the duration differs for each patient and can be as long as a day. If you are booked for shoulder surgery please remember to tell your anaesthesiologist if you chronically experience pins and needles or pain in any part of the arm or hand.

Please ask the anaesthesiologist during the pre-operative visit to clarify any uncertainty you may have.

Anaesthesiologists exercise extreme care in administering upper limb blocks but, as with any medical procedure, complications can occur. The following complications are possible:

Common complications:

1. Motor block : While we intend to block only the pain fibres we inadvertently also block the fibres that control movement. Your arm will most likely feel heavy or lame when you wake up from anaesthesia. Please do not hang your arm from the side of the bed as this can cause permanent nerve damage.
2. Horner syndrome: This happens generally when the other nerves in the area are also blocked. Commonly we see on the side of the block, a drooping eyelid, a blocked nose, small pupil, dry cheek, hoarse voice and sometimes shortness of breath in which case we send you to the ward with some oxygen . As the block wears out, these symptoms will disappear.
3. Failed block: It is possible that the block fails due to mechanical reasons or local factors in your neck or previous neck surgery. Therefore the block will provide insufficient pain relief and alternative pain methods will be employed.

Rare complications:

1. Haematoma : Because there are a few large blood vessels in that area of the neck, it is possible that one of them can be punctured while performing the block and there is a small chance that a haematoma (blood clot) can be formed.
2. Local discomfort : Sometimes it is necessary to go through some of the neck tissue to reach the nerves and this can cause some local discomfort afterwards but it is of short duration.

Very rare complications:

1. Intravenous administration : There is a small risk that the local anaesthetic can be injected directly into the

bloodstream which can lead to convulsions or heart dysrhythmias. Extreme care is exercised to prevent this complication.

2. Pneumothorax : Because the lung is situated close to the area of injection, it is possible that it can be punctured. In case of this unlikely event you will experience shortness of breath and intense chest pain, especially when breathing. An underwater tube will be placed in your chest to help you breathe.
3. Spinal or epidural : The spinal cord is also close to the area of injection and if a spinal or epidural space is accidentally injected, it can cause temporary lameness.
4. Sepsis : Although we use an aseptic technique, the possibility of a surface infection or abscess exists.
5. Nerve damage : This is possible through the insertion of the needle but is unlikely with the use of a nerve stimulator.
6. A few other extremely rare complications have also been documented in literature.

I declare that I have read and understood the contents of this information sheet and that I have discussed any uncertain aspects with the attending anaesthesiologist.

I hereby consent to having an upper limb block performed on me/ my dependant.

Signed at _____ Hospital on this the _____day of _____200__.

Signature_____ (patient/parent/guardian)

5.4 Ethics approval

UNIVERSITY OF THE
WITWATERSRAND
JOHANNESBURG

R14/49 Dr Karyll Mae San Pedro

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M190612

NAME: (Principal Investigator)	Dr Karyll Mae San Pedro
DEPARTMENT:	Anaesthesiology Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	Development and validation of an anaesthetic consent form
DATE CONSIDERED:	28/06/2019
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	H. Perrie, J. Scribante and H.J. Moutlana
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	05/09/2019

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **June** and will therefore be due in the month of **June** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

Date 10/09/2019.

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

5.2 Graduate studies approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

11 July 2019
Person No: 2051670
PAG

Dr KM San Pedro
2 Country Lodge
113 Thirteenth Avenue
Fairland
2170
South Africa

Dear Dr Karyll San Pedro

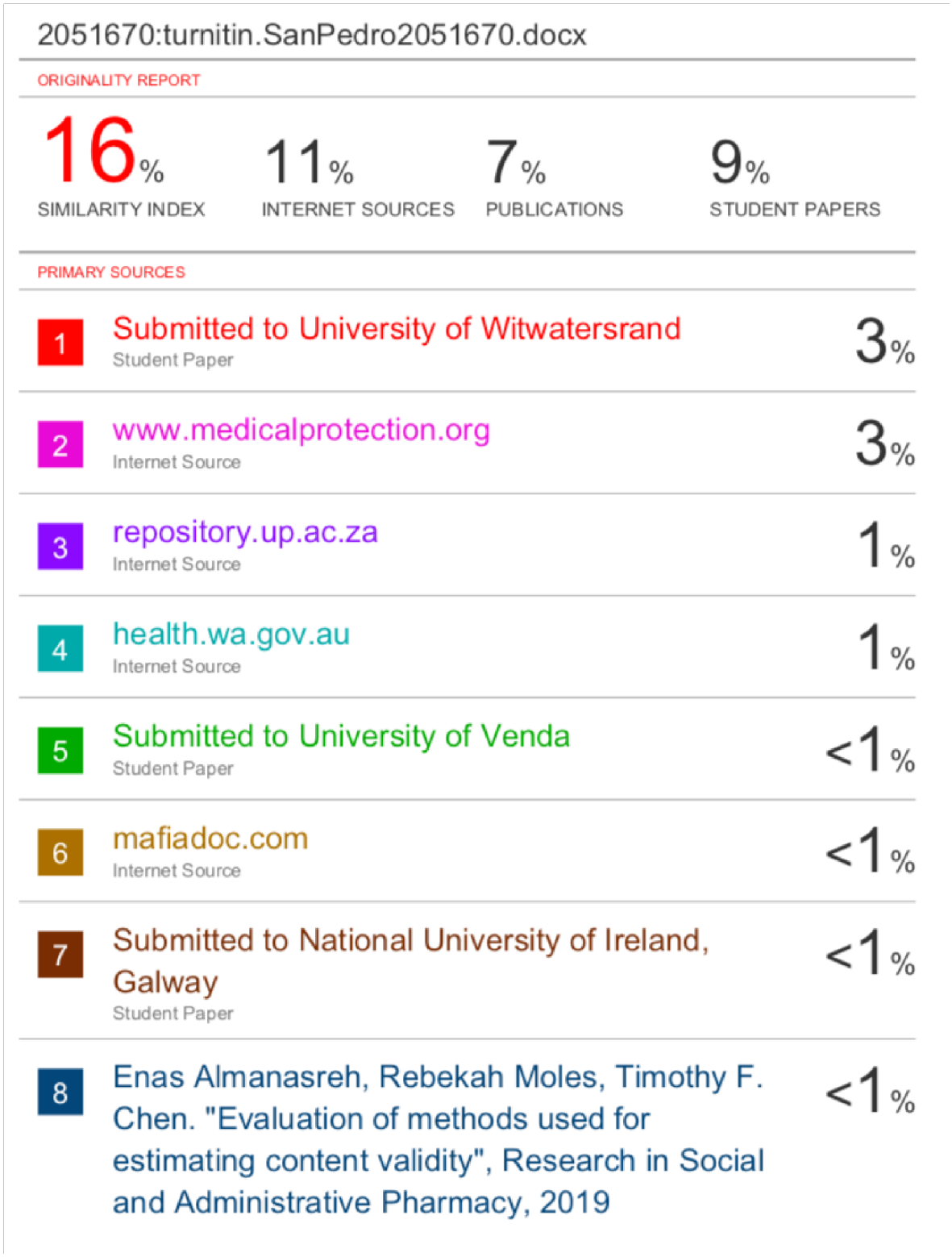
Master of Medicine in Anaesthesia: Approval of Title

We have pleasure in advising that your proposal entitled *Development and validation of an anaesthetic consent form* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

5.3 Turnitin report



2051670:turnitin.SanPedro2051670.docx

ORIGINALITY REPORT

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5.4 Letter from supervisor accompanying Turnitin report



31 August 2020

The Chairperson
Graduate Studies Committee
Faculty of Health Sciences
University of the Witwatersrand

Dear Professor Papathanasopoulos

Re: M Med: **Development and validation of an anaesthetic consent form**

Dr Karyll Mae San Pedro, student number: 2051670, has submitted her research report to Turnitin which revealed a similarity index of 16%. These similarities appear not to be plagiarism but mainly the use of common terminology and phrases specific to the topic of the research.

Yours sincerely,

Juan Scribante Supervisor